United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-95-001
March 1995

Reregistration Eligibility Decision (RED)

Ethalfluralin

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case ethalfluralin. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Tom Myers at (703) 308-8074.

Sincerely yours,

Louis P. True Jr., Acting Director
Special Review
and Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified

limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

ETHALFLURALIN

LIST B

CASE 2260

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

TABLE OF CONTENTS

ETHALFLURALIN REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Gabe Patrick	Biological Analysis Branch
Ghulam Ali	Economic Analysis Branch
Jim Saulmon	Biological Analysis Branch

Environmental Fate and Effects Division

Mary Frankenberry	Science Analysis and Coordination Staff
Bill Erickson	Ecological Effects Branch
Laura Parsons	Environmental Fate and Groundwater Branch

Health Effects Division

John Redden	Chemical Coordination Branch
Pat McLauglin	Toxicology Branch II
Laura Morris	Occupational and Residential Exposure Branch
Steve Funk	Reregistration Support Chemistry Branch
Jennifer Wintersteen	Science Analysis Branch

Registration Division

Dan Kenny	Fungicide-Herbicide Branch
Ian Blackwell	Registration Support Branch

Special Review and Reregistration Division

Tom Myers	Accelerated Reregistration Branch
Virginia Dietrich	Accelerated Reregistration Branch

Policy and Special Projects Staff

Jean Frane

Office of Enforcement:

Carol Buckingham

Office of General Counsel:

Kevin Lee

GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized As Safe as designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin Of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline

GLOSSARY OF TERMS AND ABBREVIATIONS

PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PPE	Personal Protective Equipment
ppb	Parts Per Billion
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency has completed an assessment of the potential human health and environmental risks associated with the pesticidal use of ethalfluralin in the United States. Ethalfluralin is a preemergence herbicide used to control a variety of annual grasses and broadleaf weeds on agricultural sites. The scientific data base is adequate to support the reregistration eligibility of all registered uses of ethalfluralin with the exception of postemergence and posttransplant applications to cucurbits. Residue chemistry data to support these specific methods of application are curreltly being reviewed by the Agency, 1995. The Agency has determined that the uses of ethalfluralin products, labeled and used as specified in this Reregistration Eligibility Decision Document (RED), will not cause unreasonable risk to humans or the environment.

The Agency has classified ethalfluralin as a quantifiable Group C carcinogen, based on increased mammary gland fibroadenomas and adenomas/fibroadenomas combined in female rats. The Agency estimates that the incremental, upper bound dietary risk for the U.S. population is negligible (5.7×10^{-7}). This assumes anticipated residues of ethalfluralin in all commodities except eggs, milk, fat, meat, and meat byproducts for reasons stated below. The cancer risk to mixer/loader/applicators from ethalfluralin ranges from 1×10^{-5} to 7×10^{-8} depending on the product formulation, application method, and the worker task (mixing/loading vs application). Ethalfluralin is also a developmental toxicant based on a rabbit study. However, the Agency believes dietary exposures and those to workers wearing proper personal protective equipment are such that the risks for these toxicological endpoints are acceptable.

The Agency is requiring additional technical chemistry, residue chemistry (analytical and field trial), and nitrosamine analysis data to confirm its conclusions on potential hazard and exposure. Additionally, the Agency is requiring that tolerances for eggs, milk, fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep be revoked. Due to their low levels, it is unlikely finite residues in these commodities can be determined with certainty. Personal protective equipment is being required to protect workers who handle and apply the end use products and for those who may enter treated areas before the new restricted-entry interval of 24 hours.

As currently used ethalfluralin products may pose a risk to non-endangered and endangered freshwater fish, aquatic invertebrates, and to certain nontarget plants. The Agency is requiring registrants to modify their product label directions so that risk reduction will be acheived. Use modifications include: 1) prohibiting alfalfa irrigation tail waters from entering aquatic habitats, 2) conforming to the Endangered Species Program when it takes effect, and 3) recommending the use of a vegetative filter strip for the cucurbit uses of ethalfluralin.

The Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document for all products containing ethalfluralin. These data include product chemistry and acute toxicity testing for each registration. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. However, those products which bear uses of this or any other a.i. which have not been determined to be eligible for reregistration will be reregistered only when such uses and active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of ethalfluralin. The document consists of six sections. Section I is the introduction. Section II describes ethalfluralin, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for ethalfluralin. Section V discusses the reregistration requirements for ethalfluralin. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Ethalfluralin
- **Chemical Name:** N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)-benzenamine
- **Chemical Family:** Dinitroanaline
- **CAS Registry Number:** 5523-68-6
- **OPP Chemical Code:** 113101
- **Empirical Formula:** $C_{13}H_{14}F_3N_3O_4$
- **Trade Name:** Sonalan
- **Basic Manufacturer:** DowElanco

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. This information is accurate as of September 1, 1994. A detailed table of these uses of ethalfluralin is in Appendix A.

For: Ethalfluralin

Type of Pesticide: Preemergence herbicide

Mechanism of Action: Inhibits cell division

Use Sites: Terrestrial Food Crop: Cucumber, melons, melons (water), pumpkin, squash (summer), squash (winter)

Terrestrial Food + Feed Crop: Beans (dried-type), peanuts (unspecified), peas (dried-type), soybeans (unspecified), sunflower

Terrestrial Feed Crop: Alfalfa

Target Pests:

Grassy weeds: annual bluegrass, barnyardgrass, broadleaf signalgrass, field sandbur, giant foxtail, Italian ryegrass, johnsongrass, junglerice, large crabgrass, shattercane, Texas panicum, wild oat, witchgrass, woolly cupgrass;

Broadleaf weeds: black nightshade, carpetweed, common chickweed, common lambsquarters, Florida pursley, henbit, kochia, lanceleaf groundcherry, redroot pigweed, Russian thistle, tarweed fiddleneck, wild buckwheat.

Formulation Types Registered:

Single Active Ingredient
Emulsifiable concentrate--31.5-36.1% ethalfluralin
Water dispersible granules--50% ethalfluralin
Granular--10% ethalfluralin
Technical chemical--95% ethalfluralin

Method and Rates of Application:

Emulsifiable concentrate: Soil incorporate at preplant with spreader or low pressure ground spray at 0.75 to 1.70 lb AI/A or at postemergence with low pressure spray at 1.50 to 1.70 lb AI/A; or soil broadcast at postplant with low pressure spray at 0.75 to 1.70 lb AI/A; or band at postemergence or at posttransplant with low pressure ground spray at up to 1.70 lb AI/A. .

Water dispersible granules: Soil incorporate at preplant with ground equipment at 0.75 to 1.65 lb AI/acre.

Granular: Soil incorporate in Fall or at preplant with spreader or at postemergence with low pressure ground equipment at 0.75 to 1.7 lb AI/A.

Use Practice Limitations: Do not apply to any body of water or wetland.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of ethalfluralin in the U.S. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Table 1, below, summarizes the amounts of ethalfluralin used by site.

Table 1. ESTIMATED ANNUAL U.S. USAGE OF ETHALFLURALIN

Site	Acres Planted/Harvested[a] (000)	Acres Treated[b] (000)	Percent Acres Treated[c]	Active Ingredient[c] lbs a.i. (000)	Percentage of Total a.i.
Alfalfa	24,666	< 247	< 1	10 - 50	0.4 - 1.2
Cantaloupes	131	7 - 13	5 - 10	3 - 6	0.1 - 0.1
Cucumbers	132	40 - 46	30 - 35	30 - 35	0.8 - 1.3
Dry Beans	1,918	480 - 959	25 - 50	500 - 1,000	21.7 - 23.8
Dry Peas	172	5 - 9	3 - 5	4 - 5	0.1 - 0.2
Honeydew	26	1 - 3	5 - 10	4 - 8	0.2 - 0.2
Peanuts	1,849	647 - 740	35 - 40	350 - 400	9.5 - 15.2
Soybeans[d]	58,768	1,175 - 2,938	2 - 5	1,000 - 2,000	43.5 - 47.6
Sunflower	2,289	458 - 687	20 - 30	400 - 700	16.7 - 17.4
Watermelon	251	13 - 25	5 - 10	15 - 20	0.5 - 0.7
TOTALS[e]	90,202	3,073 - 5,667		2,300 - 4,200[f]	

[a] Three years 1989-1991 or 1990-1991 average when available is reported.

[b] Acres treated are calculated from the percentages given in the imediately following two columns; The lowest limit of the ranges is zero.

[c] Sources: EPA Proprietary sources; RFF. Herbicide Use in the United States. December 1990; USDA. Agricultural Chemical Usage, 1991 Field Crops Summary, March 1992; USDA. Agricultural Chemical Usage, 1992 Field Crops Summary, March 1993; USDA. Agriculture Chemical Usage, Vegetables, 1992 Summary, June 1993.

[d] Data sources indicate a declining trend in the usage of ethalfluralin.

[e] Usage information about pumpkin and squash is not available.

[f] Total a.i. would not add up exactly because of approximation.

D. Data Requirements

In addition to data requirements imposed to obtain the original registration of this active ingredient, data were required in the reregistration Phase IV Data Call-In issued in December of 1990. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Ethalfluralin is the accepted common name for N-ethyl-N-(2- methyl-2-propenyl) -2,6-dinitro-4-(trifluoromethyl)-benzenamine. It is manufactured by DowElanco and is marketed under the trade name Sonalan.

Ethalfluralin is a selective herbicide for the preemergence control of certain annual grasses and broadleaf weeds. It was initially granted a conditional registration in in November 1983 until December 1, 1985 for use on dry peas, dry beans, soybeans, and the cucurbits vegetable group to control weeds. A risk-benefit analysis, as described in the Federal Register v. 49, No. 2:29-33 and published concurrently, determined that the benefits outweighed the dietary and worker carcinogenic risks for the period of the conditional registration. Tolerances were also established at this time in a companion notice. Subsequently, adequate data were submitted to allow full registration of ethalfluralin and additional uses have been added since, including sunflowers seeds in 1985 and peanuts and peanut hulls in 1987.

In December of 1990 the Agency issued a Data Call-In Notice under Phase IV of reregistration, requiring registrants to submit additional generic data to support reregistration.

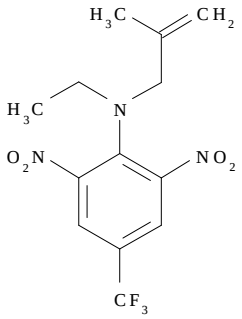
As of September 1, 1994, there are six active products containing ethalfluralin which are registered under Section 3 of FIFRA. They consist of a 95% technical (manufacturing use) product, two 36.1% emulsifiable concentrate end-use products, one 31.5% emulsifiable concentrate end-use product, one 50.0% water dispersible granular end-use product, and one 10.0% granular end-use product.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Ethalfluralin [*N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)-benzenamine] is a selective preemergence herbicide registered for use on a variety of food and feed crops. The ethalfluralin formulations registered for use on these crops include the granular (G), the dry flowable (DF), and the emulsifiable concentrate (EC). These formulations may be applied preplant, postplant prior to emergence, postemergence, or post-transplant as a soil incorporated, band, or broadcast application using ground equipment. Ethalfluralin is only used outdoors.

Ethalfluralin [N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl) benzenamine] has the following chemical structure:



Empirical Formula:	$C_{13}H_{14}F_3N_3O_4$
Molecular Weight:	333.27
CAS Registry No.:	55283-68-6
Shaughnessy No.:	113101

Ethalfluralin is a yellow crystalline solid with a melting point of 57°C. Ethalfluralin is readily soluble in organic solvents (acetone, acetonitrile, benzene, chloroform, hexane, methanol, methylene chloride, and xylene), and is soluble in water at 0.3 ppm at 25°C.

The following Technical Chemistry data are required to confirm the qualitative and quantitative nature of technical ethalfluralin and possible impurities from the manufacturing process:

- (61-1) Product Identity and Disclosure of Ingredients: Submitted data do not fully satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product identity because two compounds were incorrectly identified on the Confidential Statement of Formula (CSF). Furthermore, the registrant must provide definitive chemical names for all "isomers" and CAS numbers for all components.

- (62-1) Preliminary Analysis: These data do not fully satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis because preliminary analysis data on five samples from different batches of the 96% Technical, manufactured using the current manufacturing process, must be submitted. If the manufacturing process has changed from the one previously reviewed by the Agency in 1992, then the registrant must submit a complete description of the manufacturing process for review (under GLN 61-2). The registrant must also indicate how the components of a group of impurities (active ingredient isomers) were distinguished and confirm the identification of one compound listed on the CSF from the tentative identification made in preliminary analysis. In addition, the nitrosamine analysis must be performed using a sample analyzed at 0, 3, and 6 months after production; only an initial analysis was

provided. Finally, the registrant must submit preliminary analysis data for an impurity included on the CSF dated 5/26/92.

- (62-2) Certification of Ingredients: Submitted data do not fully satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certification of limits because a lower certified limit must be proposed for an impurity which is pesticidally active. We note that this compound should also be added to the label claim. In addition, the registrant must identify which of the two manufacturing processes discussed in preliminary analysis the proposed certified limits are intended to support.

- (62-3) Analytical method to Verify the Certified Limits: Submitted data do not fully satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods because complete validation data must be submitted for the method used to determine the active ingredient. In addition, the registrant must submit a complete description and supporting validation data for the analytical methods used to determine the impurities.

Provided that the registrant submits the data required for guidelines 61-1, 62-1, 62-2, and 62-3, for DowElanco ethalfluralin 96% Technical, as described above and either certifies that the suppliers of starting materials and the manufacturing process for ethalfluralin have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, ethalfluralin is eligible for reregistration with respect to product chemistry data requirements.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base on ethalfluralin is adequate and will support reregistration eligibility.

a. Acute Toxicity

Table 2.

TEST	RESULTS	CATEGORY
Oral LD_{50}--rat	LD_{50} > 5000 mg/kg	IV
Dermal LD_{50}--rabbit	LD_{50} > 5000 mg/kg	IV
Inhalation LC_{50}--rat	LC50 > 0.94 mg/L	III
Eye irritation--rabbit*	moderate	II
Dermal irritation--rabbit*	moderate to severe	II
Skin sensitization-- guinea pig*	sensitizer	---

* Note: Data pertaining to primary eye irritation, primary dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented for informational purposes.

An acute oral toxicity study with rats found the LD_{50} was greater than 5000 mg/kg, which was toxicity category IV (MRID 41613908). An acute dermal toxicity study with rabbits found the LD_{50} was greater than 5000 mg/kg. This was toxicity category IV (MRID 41613909).

An acute inhalation study with rats found the LC_{50} was greater than 0.94 mg/L, which was toxicity category III (MRID 41977601). An eye irritation study with rabbits found slight to moderate corneal opacity and edema with slight to severe iritis and irritation up to the third day, generally followed by clearing by the seventh day. One animal retained scattered opacity through day 7, clearing by day 14. This was toxicity category II (MRID 41613910). A dermal irritation study with rabbits found slight to moderate irritation and edema from 24 hours through 7 days after 24 hour dermal treatment. There were desquamation, slight to severe edema and irritation, with coriaceous formation, through 14 days. One animal had epidermal fissures and bleeding by the fourteenth day. This was toxicity category II (MRID 41613909).

A guinea pig dermal sensitization study conducted by the modified Buehler method found no sensitization, whereas a study conducted by the Magnusson and Kligman maximization method found ethalfluralin was positive (MRID 00094788, ACC 070683a).

b. Subchronic Toxicity

A three month feeding study with B6C3F1 mice used doses of 0, 560, 1110, 2250, 4000, or 8000 ppm (68, 136, 285, 538, or 1205 mg/kg/day). The NOEL was 560 ppm. The LOEL was 1110 ppm based on low bilirubin and low kidney weights in males. Higher doses showed depressed weight gain, increased serum glutamic pyruvic transaminase (SGPT), increased serum alkaline phosphatase, and increased relative liver weights. (MRID 00094774)

In a second study, ethalfluralin was administered to B6C3F1 mice for one year at dietary concentrations of 0, 100, 400, or 1500 ppm (equivalent to 0, 12, 47.0, or 173 mg/kg/day for males; 0, 12, 49, or 184 mg/kg/day for females). The NOEL was 100 ppm. The LOEL was 400 ppm, based on increased alkaline phosphatase levels at this and the high dose. At the high dose, there were decreased blood urea nitrogen (BUN) and creatinine, increased SGPT, and increased relative liver weights. (MRID 00094778)

In a third study, ethalfluralin was fed to Fisher 344 rats for one year. The doses were 0, 100, 250, or 750 ppm in the diet (equivalent to

0, 3.9, 9.7, or 28.4 mg/kg/day for males; 0, 4.9, 11.9, or 34.4 mg/kg/day for females). The NOEL was 100 ppm. The LOEL was 250 ppm, based on blood chemistry changes at the two higher doses, with increased relative liver weights and decreased body weight gain at the high dose. (MRID 00094775)

The doses for the preceding study, and for the two year rat study discussed below, were derived from a three month study in which Fischer 344 rats were fed 0, 250, 500, 1100, 2500, or 5000 ppm test material. The NOEL was 500 ppm (29 mg/kg/day). Higher doses showed increased liver and kidney weights, lower red blood cells (RBC), hematocrit and hemoglobin, as well as some enzyme activity changes (MRID 00135191). Although this is a supplemental study it provides the rationale for dose selection in the above mentioned studies.

A three month oral study with beagle dogs had doses of 0, 6.25, 27.5, or 125/80 mg/kg/day by capsule. The systemic NOEL was 27.5 mg/kg/day. The systemic LOEL was 80 mg/kg/day (the high dose) based on elevated alkaline phosphatase, slight fatty metamorphosis of the liver, increased cholesterol, and increased BUN. (MRID 00135193)

In a 21 day dermal toxicity study, New Zealand white rabbits were treated with 0 or 1000 mg/kg/day, a limit dose. No systemic effects were found at this dose; skin effects were slight to severe dermal irritation, as well as edema and coriaceous skin with epidermal fissures. (MRID 00145767)

c. Chronic Toxicity and Carcinogenicity

Ethalfluralin was administered to Fisher 344 rats in the diet for two years in combined chronic toxicity and carcinogenicity replicate studies. The doses were 0, 0.01, 0.025, or 0.075 percent in the diet (equivalent to 0, 4.2, 10.7, or 32.3 mg/kg/day). The NOEL for systemic effects was 32.3 mg/kg/day, the high dose. Mammary gland fibroadenomas were found in dosed female rats at statistically significant incidences in the mid and high doses. (MRID 00094776 and 92062013)

Ethalfluralin was administered to B6C3F1 mice in the diet for two years in combined chronic toxicity and carcinogenicity replicate studies. The doses were 0, 100, 400, or 1500 ppm in the diet (equivalent to 0, 10.3, 41.9, or 163.3 mg/kg/day). No increased incidence of neoplasms was attributed to the treatment. The NOEL was 10.3 mg/kg/day. The mid dose (LOEL) and high dose showed focal hepatocellular hyperplasia in both sexes. There were increased relative liver, kidney, and heart weights in

females. Some blood changes were found also, including decreased hematocrit, hemoglobin, and erythrocyte count accompanied by increased mean corpuscular hemoglobin concentration in high dose females. Alkaline phosphatase values were increased at the high dose in both sexes. Body weight gain decreased at the high dose. (MRID 00094777 and 92062016)

Beagle dogs were given 0, 4, 20, or 80 mg/kg/day orally, by capsule, for one year. The NOEL was 4 mg/kg/day. The LOEL was 20 mg/kg/day, based on increased urinary bilirubin, variations in erythrocyte morphology, increased thrombocyte count, and increased erythroid series of the bone marrow. Elevated alkaline phosphatase levels were found at the two higher doses and siderosis of the liver at the high dose (MRID 00153371 and 92062014)

The Agency's Office of Pesticide Program's Carcinogenicity Peer Review Committee on June 8, 1994, concluded that ethalfluralin should be classified as Group C, a possible human carcinogen, based on increased mammary gland fibroadenomas and adenomas/fibroadenomas combined in female rats. The tumor incidences were statistically significant at both the mid and high dose, and were well in excess of the upper range of historical controls. Based on a low dose extrapolation, the upperbound unit risk, Q_1^* of ethalfluralin is 8.9×10^{-2} $(mg/kg/day)^{-1}$.

d. Developmental Toxicity

Ethalfluralin was administered orally to Sprague Dawley rats at 0, 50, 250, or 1000 mg/kg/day on gestation days 6-15. The maternal NOEL was 50 mg/kg/day. The maternal LOEL was 250 mg/kg/day, based on decreased body weight gain and dark urine. In this study there was no observable developmental toxicity. The developmental NOEL was 1000 mg/kg/day, the highest dose. (83-3; MRID 0015337 and 92062017)

Dutch Belted rabbits were given 0, 25, 75, 150, or 300 mg/kg/day of ethalfluralin by gavage on gestation days 6-18. The NOELs for maternal and developmental toxicity were 75 mg/kg/day. The maternal LOEL at 150 mg/kg/day was based on abortions and decreased food consumption. These effects as well as decreased weight gain, enlarged liver, and orange urine were found at 300 mg/kg/day. In this study developmental toxicity was observed. The developmental LOEL was 150 mg/kg/day, based on slightly increased resorptions, abnormal cranial development, and increased sternal variants. (MRID 00129057)

e. Reproductive Toxicity

A three-generation reproduction study in Fischer 344 rats gave doses of 0, 100, 250, or 750 ppm in the diet (equivalent to 0, 5.0, 12.5, or 37.5 mg/kg/day). The parental NOEL was 12.5 mg/kg/day. The parental LOEL was 37.5 mg/kg/day, based on depressed mean body weight gains in males in all generations. No treatment-related effects were noted on reproductive parameters and the NOEL was 37.5 mg/kg/day or greater. (MRID 00094784 and 92062019)

A seven month multigeneration bridging study was conducted with doses of 0, 100, 250, or 750 ppm (equivalent to 0, 8, 20, or 61 mg/kg/day) in the diet of Fischer 344 rats. The parental NOEL was 20 mg/kg/day. The parental LOEL was 61 mg/kg/day, based on increased liver weights. No treatment-related effects were noted on reproductive parameters and the reproductive NOEL was equal to or greater than 61 mg/kg/day (MRID 42300301).

f. Mutagenicity

Ethalfluralin was weakly mutagenic in activated strains TA1535 and TA100 of Salmonella typhimurium but not in strains TA1537, TA1538, and TA98 in an Ames assay. In a modified Ames assay with Salmonella typhimurium and Escherichia coli, ethalfluralin was weakly mutagenic in strains TA1535 and TA100, with and without activation, and in strain TA 98 without activation, at the highest dose (MRID 00128693 and 00128694). No mutagenicity was found in the mouse lymphoma assay for forward mutation (MRID 00128696). Ethalfluralin did not induce unscheduled DNA synthesis in rat hepatocytes (MRID 00128695). In Chinese hamster ovary cells, the chemical was negative without S9 activation, but it was clastogenic with activation (MRID 00152219).

g. Metabolism

Fischer 344 rats were treated orally with a single low dose, a single high dose, or repeated low doses of radiolabeled ethalfluralin. Absorption of ethalfluralin was estimated at 79-87% of the dose for all dose levels. Ethalfluralin was rapidly and extensively metabolized, and 95% of the chemical was excreted in urine and feces by seven days. The major route of elimination for the radiolabel was in the feces, 50.9-63.2%, and the levels remaining in the tissues after 72 hours were negligible. The major metabolites in urine and feces were identified. (MRID 42822901)

A study with Rhesus monkeys indicated that 2.8% of a dermal dose was absorbed through the skin (MRID 00132820).

h. Reference Dose

The RfD was determined to be 0.04 mg/kg/day, based on a NOEL of 4.0 mg/kg/day (altered red cell morphology, increased urinary bilirubin) in the one-year oral dog study (MRIDs 00153371 and 92062014) discussed above. An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability. There has been no WHO RfD determination as of yet.

2. Exposure Assessment

a. Dietary Exposure

Tolerances for residues in/on plants (dry beans, cucurbit vegetables group, peanuts, peanut hulls, dry peas, soybean, and sunflower seed) and in animal commodities (eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep) are expressed in terms of ethalfluralin *per se* [40 CFR §180.416]. All of these tolerances are established at 0.05 ppm and are listed in Section IV, Table 19. No food/feed additive tolerances have been established. Adequate enforcement methods are available for the determination of ethalfluralin residues in/on plant and animal commodities.

GLN 171-3: Directions for use

According to the Agency's records, there are five ethalfluralin end-use products (EPs) with food/feed uses which are registered to DowElanco and Platte Chemical Company. Restrictions on grazing, foraging, haying for beans, peas, soybeans, peanuts, and alfalfa must be removed from all labels as detailed below in the discussion of guideline 171-4(k): Magnitude of the Residue in Plants.

GLN 171-4 (a): Plant Metabolism

The qualitative nature of the residue in beans and peanuts is understood. These studies (MRID 00145955, 00094754, and 43394001) were conducted under the registered use patterns. Sufficient radioactive residues in/on bean and peanut commodities were obtained following preplant soil-incorporated application of uniformly ring-labeled [^{14}C]ethalfluralin at ~ 1x the maximum registered rate. The major portion

of the radioactivity was characterized as lignin, cellulose, and protein. The parent, ethalfluralin, was a minor residue.

The tentatively terminal residue of concern in plants is ethalfluralin *per se*; the current tolerance expression for plants is adequate. However, before plant metabolism may be considered fully understood, an acceptable cucurbit metabolism study must be submitted. A cucurbit metabolism study is on-going. The cucurbit study and the outstanding raw data for the peanut and bean studies will be considered confirmatory.

GLN 171-4 (b): Animal Metabolism

The qualitative nature of the residue in animals is adequately understood based on acceptable poultry and ruminant metabolism studies. In the poultry metabolism study, laying hens were dosed with uniformly ring-labeled [^{14}C]ethalfluralin at 10 ppm in the diet (about 200x the maximum theoretical dietary burden) for ten consecutive days. The maximum total radioactive residues were 0.169 ppm in eggs, 0.697 ppm in liver, 0.070 ppm in muscle, and 0.194 ppm in skin. The parent compound, ethalfluralin, was the major compound identified in skin, but was a minor component in eggs, liver, and muscle. Four other metabolites, 2,6-dinitro-4-(trifluoromethyl)phenol, N-ethyl-2,6-dinitro-4-(trifluoromethyl)benzenamine, N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine, and 2,6-dinitro-4-(trifluoromethyl)benzenamine, were identified; each identified metabolite was present at $\geq$ 0.05 ppm.

In the ruminant metabolism study, a lactating dairy cow was dosed with uniformly ring-labeled [^{14}C]ethalfluralin at 10 ppm in the diet (about 200x the maximum theoretical dietary burden) for three consecutive days. The total radioactive residues were 0.011 ppm in fat, 0.050 ppm in kidney, 0.104 ppm in liver, 0.002 ppm in muscle, and up to 0.006 ppm in milk. Ethalfluralin was identified in milk and fat; neither parent nor metabolites were identified in kidney or liver.

The residue of concern in milk, eggs, and animal tissues is ethalfluralin *per se*. As a result of the low levels of radiolabeled residues found with the exaggerated (200x) feeding levels, the requirements for animal feeding studies were waived. It was also concluded that residues of ethalfluralin from up to 10x dietary burden would not be quantifiable (< 0.05 ppm). Therefore, according to 40 CFR 180.6(a)(3), if it is not possible to determine finite residues with certainty, and it is unlikely there are any residues, tolerances should not be established for eggs, milk, fat

and meat byproducts of cattle, goats, hogs, horses, poultry and sheep. Thus, these existing tolerances should be revoked.

GLN 171-4 (c) and (d): Residue Analytical Methods-Plants and Animals

Adequate residue analytical methods are available for purposes of reregistration. Two GC methods, Method I and II, both with electron capture detection (ECD) are listed in the Pesticide Analytical Manual (PAM, Vol. II, Section 180.416) for tolerance enforcement. Method I is applicable for the analysis of ethalfluralin residues in/on plant commodities (cottonseed, cucurbits, forage legumes, peanuts, seed and pod vegetables, and sunflower seed). Method II is applicable for tolerance enforcement of ethalfluralin residues in animal commodities (eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep). The limits of detection are 0.01 ppm and < 0.01 ppm, for Method I and Method II respectively.

The principal analytical method used for residue data collection in plant commodities was the enforcement method, Method I. Adequate concurrent method recoveries (70-120%) support the results of field residue and storage stability studies that were used for tolerance reassessments. The qualitative nature of the residue in cucurbits has not been adequately described. If the requested data on cucurbit metabolism indicate the presence of additional metabolites of toxicological concern, then relevant additional analytical methods and data may be required.

Representative samples from the submitted bean and peanut metabolism studies were not analyzed using the current enforcement method. However, since no additional terminal residues of concern were found in dried bean stems and peanut nutmeats and hulls, radio-validation data will not be needed.

The FDA PESTDATA database dated August 1993 (PAM Vol. I, Section 180.416) indicates that ethalfluralin is completely recovered (> 80%) using multiresidue method protocols D and E (fatty and nonfatty).

GDLN 171-4 (e): Storage Stability

Storage stability studies have been conducted using fortified samples of beans (dry), cucumbers, peanuts, peas (dry), soybean, soybean processed commodities, and sunflower seed. Residues of ethalfluralin are stable under frozen storage conditions (-20 C) in/on beans (dry), soybean processed commodities, and sunflower seed for up to 6 months, in/on peas (dry) for up to 10 months, and in/on cucumbers, peanuts, and soybean for

up to 12 months. Storage stability data for soybean processed commodities may be translated to peanut processed commodities. Storage stability data for cucumbers may be translated to melons, pumpkin, squash (summer and winter), and watermelon.

Additional confirmatory data indicate that ethalfluralin residues are stable in sunflower seed stored at room temperature and then frozen, reflecting sample handling which occurred during the sunflower seed crop field trial study.

Samples of eggs, milk, and tissues from the poultry and ruminant metabolism studies were analyzed within two months of sample collection. Therefore, storage stability data to validate the results from the animal metabolism studies are not required.

GLN 171-4 (k): Magnitude of the Residue in Plants

All data requirements for magnitude of ethalfluralin residue in plants have been evaluated and deemed adequate except for cucurbits and the forage and hay of various crops. To support the use on cucurbits data from residue field trials on cucumbers, squash, and melons are required to fulfill the data requirements. This data is currentl being reviewed by the Agency.

The registered uses of ethalfluralin on beans (dry), peanuts, peas (dry), soybean, and sunflower along with the established tolerances on these commodities are supported by acceptable field residue data from trials reflecting the maximum registered use patterns. In all cases, the residues were < 0.01 ppm. Field trial studies for cucurbits, specifically summer and winter squash, pumpkins, cucumbers, and melons, are being conducted. Previous studies, not submitted by the registrants for reregistration purposes, indicated that residues were nondetected (< 0.01 ppm) in/on squash, cantaloupe, cucumber, watermelon, and pumpkin from postplant-preemergence surface application at rates of 1.25 - 2.5 lbs. a.i./acre. The similarity of the postplant-preemergence use pattern among crops and the comparability of residue results (< 0.01 ppm) combined with the previous field trial results provide adequate data to support the existing tolerance of 0.05 ppm for residues of ethalfluralin in/on cucurbits for postplant-preemergence use only until new field trial studies are submitted within one year. The postemergence and post-transplant uses on cucurbits are not similar to other crop use patterns. A registrant is conducting studies to support all uses on cucurbits. At this time, without data, the postemergence and posttransplant uses of ethalfluralin on cucurbits is not eligible for reregistration. If data from these studies are

not adequate, unsupported uses will need to be removed from product labels.

As the result of recent changes in Table 2, Subdivision O (6/94), label restrictions on grazing, haying, and foraging are generally no longer permitted. Field trial data are required for residues of ethalfluralin in/on alfalfa forage and hay, bean forage and hay, pea forage and hay, peanut hay, and soybean forage and hay. These data are necessary to confirm the adequacy of the established tolerances.

GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for processing studies are fulfilled. Adequate processing studies have been conducted on the following RACs: peanuts, soybean, and sunflower seed. Field residue data resulting from up to 5x label rates show nondetectable (< 0.01 ppm) residues of ethalfluralin in peanuts, soybean, and sunflower seed. For the purposes of reregistration, it is concluded that residues are not likely to concentrate in the processed commodities of peanuts, soybean, and sunflower seed. No food or feed additive tolerances are required.

GLN 171-4 (j) Magnitude of the Residue Meat, Milk, Poultry, and Eggs

The data requirements for magnitude of ethalfluralin residue in meat, milk, poultry, and eggs have been waived. The results of nature of the residue studies in poultry and ruminants, using exaggerated feeding rates (200x) indicate that residues of ethalfluralin at levels 1-10x the dietary burden will not be quantifiable (< 0.05 ppm). Therefore, since it is not possible to establish with certainity whether finite residues will be incurred, but there is no reasonable expectation of finite residues (40 CFR §180.6), the existing tolerances (expressed in terms of ethalfluralin *per se*) for eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep should be revoked as mentioned above under GDLN 171-4(b):Animal Metabolism.

GLN 165-1 and 165-2: Confined/Field Rotational Crops

A confined rotational crop study has been submitted and deemed adequate. In that study, radioactive residues were > 0.01 ppm in/on mature commodities of rotational crops (root crops, leafy vegetables, and small grain) grown in soils that had been treated with [phenyl-^{14}C]ethalfluralin at 1x the maximum registered rate. Ethalfluralin at 0.01 ppm (2.3% TRR) was found in only one sample of mature barley chaff from the 30-day plantback interval. Ethalfluralin was not identified in any

other plant commodity at any plantback interval. The major metabolite, designated as Unknown 1, was found at 0.03-0.11 ppm (18-83% TRR) and was characterized to be polar in nature but not a potential residue of concern. Field rotational crop studies are not required since no residues of concern were found at significant levels in rotational crops. Furthermore, tolerances for rotational crop commodities and plantback restrictions need not be established.

b. Occupational and Residential

Use patterns

As stated previously, ethalfluralin is a herbicide formulated as a granular (containing 10 percent a.i.), dry flowable (50 percent a.i.), and as several emulsifiable concentrates (containing 31.5 percent to 36.1 percent a.i.). It is applied as a band or broadcast treatment using low-pressure groundboom or granular spreader equipment as specified above in Section II.B. All products containing ethalfluralin are primarily for occupational use.

The Agency's 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Such uses include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food and feed crops). Uses within scope of WPS include uses on plants and uses on the soil or planting medium the plants are (or will be) grown in. At this time all of the registered uses of ethalfluralin appear to be within the scope of the WPS.

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete. Because ethalfluralin is classified as a Group C carcinogen, the toxicology criteria are triggered.

Handlers (Mixers/Loaders/Applicators) Exposure

There is potential exposure to handlers during use of ethalfluralin products. There is a concern about potential exposures arising from mixing and loading liquid or dry flowable formulations, from loading granular

formulations, and from applying with groundboom and granular spreader equipment.

Requirements for mixer/loader/applicator (i.e., handler) exposure studies are addressed in Subdivision U of the Pesticide Assessment Guidelines. Mixer/loader/applicator (M/L/A) exposure data for ethalfluralin were not required during Phase IV of the reregistration process, since no new toxicological criteria were noted at that time. A review of the toxicological data, summarized above, indicates that criteria for requiring exposure data are met. An exposure assessment is required since ethalfluralin is now classified as a quantifiable Group C carcinogen. Surrogate and chemical specific data are available to conduct an exposure assessment and additional data are not required.

Ethalfluralin M/L/A data for the granular formulation (Edge 5G) were developed by the registrant for Health Canada and were also submitted to the U.S. Pesticide Handler Exposure Database (PHED). A limited exposure/risk assessment for handlers of all formulations and application methods was conducted for ethalfluralin using that data and other generic data obtained from PHED.

Based on the use-patterns and potential exposures described above, four major exposure scenarios are identified for ethalfluralin: (1) mixing/loading the liquid/dry flowable formulation, (2) loading the dry (granular) formulation, (3) applying the liquid/dry flowable formulation with a groundboom sprayer, and (4) applying the dry formulation with granular spreader equipment. The exposure scenarios are presented in Table 3 along with the corresponding exposure/risk assessment. Table 4 summarizes the caveats and parameters specific to each exposure scenario. For consistency, protection factors were applied to the exposure data reported in Table 3 to simulate personal protective equipment use of coveralls and chemical-resistant gloves, since the actual clothing and equipment worn by persons being monitored in the exposure studies (described in Table 4) included long sleeves and pants or coveralls and chemical resistant gloves or no gloves.

Table 3. Summary Exposure/Risk Values for Ethalfluralin

Exposure Scenario (Scen. #)	Dermal Exposure[a] mg/lb ai	Inhalation Exposure[b] µg/lb ai	Maximum Label Application Rate[c] lb/ai acre	Daily Max[d] Treated (acres)	Daily Dermal Dose[e] mg/kg/day	Commercial Mixer/Loader/ Applicator[g]	
						Dermal LADD[f] mg/kg/day	RISK[h]
Mixer/Loader Exposure							
Liquids/Dry Flowable (Ground Application) (I)	0.2	0.4	1.7	80	0.39	$1x10^{-4}$	$1x10^{-5}$
Granules (Ground Application) (II)	0.007*	1.0	1.7	80	0.014	$6x10^{-6}$	$5x10^{-7}$
Applicator Exposure							
Groundboom Application (II)	0.02	1.3	1.7	80	0.039	$1x10^{-5}$	$1x10^{-6}$
Solid Broadcast (Tractor) (IV)	0.0008	0.1	1.7	80	0.002	$8x10^{-7}$	$7x10^{-8}$

[a] Dermal unit exposures are reported as the best fit mean to simulate workers wearing coveralls and chemical resistant gloves. The best fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types. The ethalfluralin generated mixer/loader and applicator data are reported as the geometric mean. Protection factors were used to calculate dermal exposure values because insufficient data are available for PPE in these scenarios. Fifty percent of the total dermal exposure is assumed to be attributed to hand exposure. Fifty percent protection factor is applied to the hand exposure for chemical resistant gloves.

[b] Inhalation exposure values are reported as geometric means (lognormal distribution). No adjustment has been made to simulate workers wearing dust/mist respirators. Inhalation exposure (µg/lb ai) is considered to be significantly less than potential dermal exposure.

[c] Label Use Information System report and ethalfluralin labels.

[d] Values represent the maximum area which is assumed to be used in a single day to complete treatments for each exposure scenario of concern.

[e] Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai) x Max. Appl. Rate (lb ai/acre) x Max. Treated}}{70 \text{ kg}}$

[f] LADD (mg/kg/day) = Daily Dermal Dose (mg/kg/day) x (10 Work Days Per Yr/365 Days Per Year) x (35 Yrs/70 Yrs) x 0.028 (dermal absorption)

[g] Commercial applicator is defined as an intermediate exposed individual (i.e., 10 days).

[h] Risk = Dermal LADD (mg/kg/day) x Q_1*

* No protection factor necessary

Table 4. Exposure Scenario Descriptions for Ethalfluralin

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario[a]	Equipment	Standard Assumptions[b] (8-hr work day)	Comments[c]
Mixer/Loader Exposure					
Liquids/Dry Flowables for Ground Application (I)	PHED	Long Pants, Long-Sleeved Shirt, No Gloves	Open Mixing	80 acres	Acceptable grades; Dermal = 14+ replicates; Inhalation = 40 replicates High confidence in data
Granules for Ground Application (II)	Dow Elanco	Single layer coveralls, Gloves	Open Mixing	80 acres	Acceptable dermal grades; Inhalation grades 25A and 5C; Dermal = 24 replicates; Inhalation = 30 replicates High confidence in data
Applicator Exposure					
Groundboom Application (II)	PHED	Long Pants, Long-Sleeved Shirt, No Gloves	Open cab	80 acres	Grades A, B, C; Dermal = 6+ replicates Inhalation = 56 replicates Low - Medium confidence in data
Solid Broadcast - Tractor (V)	Dow Elanco	Single layer coveralls, No gloves	All but four replicates closed cab; both cultivator mounted and pull-behind applicator equipment	80 acres	Acceptable dermal grades; Inhalation grades 24A and 5C; Dermal = 27 replicates; Inhalation = 29 replicates High confidence in data

[a] Clothing scenario represents actual monitored exposure data. The dermal exposure values on Table 1 have been adjusted using protection factors to simulate long pants, long-sleeved shirt and chemical resistant gloves.

[b] Standard Assumptions based on an 8-hour work day as estimated by the Agency.

[c] "Acceptable grades," as defined by the Agency's SOP for meeting Subdivision U Guidelines, are grades A and B for dermal inhalation, and grade C for hand rinse method. All grades that do not meet the Agency's SOP are listed individually.

Post-Application Exposure

The Agency has determined that there is potential exposure to persons entering treated sites after application is complete, only under one of the following conditions: (1) the application is not incorporated correctly or (2) the entry task involves contact with the soil subsurface.

The potential exposure to persons entering treated sites after application should be minimal and does not trigger a need for dislodgeable residue studies.

3. Risk Assessment

Toxicological Endpoints

Because ethalfluralin demonstrated developmental toxicity in rabbits (from acute dosing), developmental toxicity is an appropriate endpoint for acute dietary risk assessment for this chemical. The NOEL for this risk assessment is 75 mg/kg/day from the developmental toxicity study. The effects seen at 150 mg/kg/day LOEL were increased resorptions and increased sternal and cranial variations. Developmental toxicity is not an appropriate endpoint of concern for occupational/residential exposure because the dermal absorption rate, 2.8% (from the Rhesus monkey study), is too low to cause concern for short term exposure.

For chronic dietary exposure, ethalfluralin has a Reference Dose (RfD) of 0.04 mg/kg body weight/day based on a NOEL of 4.0 mg/kg/ day from the one year dog study and an uncertainty factor of 100. Additionally for chronic exposure, ethalfluralin has been classified as a possible (Group C) human carcinogen based on conclusions of the two year rat study. A cancer risk assessment using the Q_1^* of 8.9×10^{-2} $(mg/kg/day)^{-1}$ is appropriate.

a. Dietary

Food uses in this analysis include all published tolerances listed in the Tolerance Index System (TIS) (see Table 19, below) and 40 CFR §180.416. All established tolerances are 0.05 ppm ethalfluralin. Although adequate data are not available for the reregistration of ethalfluralin on cucurbits, the Agency considered the existing published tolerances for cucurbits in its analysis, as the worst case scenario.

Currently tolerances exist for fat, meat and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep as well as milk and eggs. Although the Agency is requiring in this document the revocation of these tolerances for the reasons stated above, they were included in the acute, chronic, and carcinogenic assessments, again, as a worst case assumption.

Acute Exposure

The Agency's Dietary Risk Evaluation System (DRES) detailed analysis for acute exposure evaluates individual food consumption as reported by respondents in the USDA 77-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis assumes uniform distribution of ethalfluralin in the commodity supply. Since developmental toxicity is the toxicological effect to which high end exposure is being compared in this analysis, the DRES subgroup of concern is females (13+ years) which approximates women of child-bearing age.

The Margin of Exposure (MOE) is a measure of how closely the high end exposure is to the NOEL (the highest dose at which no effects were observed in the laboratory study). It is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). For substances whose acute NOEL is based on animal studies, the Agency believes MOEs of 100 or greater represent a negligible risk to that toxicological endpoint.

In the analysis, the Theoretical Maximum Residue Contribution (TMRC) or tolerance level residues were used to estimate the high-end dietary exposure for the females (13+ years) subgroup. This exposure is 0.003 mg/kg/day. High end exposure was compared to the NOEL of 75 mg/kg bwt/day from the rabbit developmental study to get a high end Margin of Exposure. The MOE for females was calculated in the attached table and the results are as follows:

NOEL/ Exposure = 75 mg/kg/day ÷ 0.003 mg/kg/day = 25,000

Using the given endpoints, the MOE is not of concern for the subgroup females (13+ years) with an estimated MOE of 25000.

Chronic Exposure

The DRES chronic analysis used tolerance level residues to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Of these subgroups, non-nursing infants is the most highly exposed subgroup. Refinements in residue and percent crop treated information were considered in calculating the Anticipated Residue Contribution (ARC) for those same population groups. The ARC is considered the more accurate estimate of dietary exposure. These residue values are listed in Section IV, Table 20. These

exposure estimates were then compared to the RfD for ethalfluralin to calculate estimates of chronic dietary risk.

Using Tolerances:

The Theoretical Maximum Residue Contribution (TMRC) (exposure in mg/kg/day) for the overall U.S. population from published tolerances are listed below.

Population group	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.000735	2
Non-nursing Infants	0.003565	9

Using Anticipated Residues:

The Anticipated Residue Contribution (ARC) for the overall U.S. population from the published uses recommended through reregistration are listed below.

Population group	Exposure(mg/kg/day)	%Reference Dose
U.S. population	0.000699	2
Non-nursing Infants	0.00347	4

The U.S. population and all the DRES subgroups have ARCs for chronic dietary risk well below the RfD when all tolerances or anticipated residues are considered.

Carcinogenicity Risk

The upper bound carcinogenic risk from food uses of ethalfluralin were calculated using the following equation:

Upper Bound Cancer Risk = Dietary Exposure (ARC) x Q_1^*

Based on a Q_1^* of 0.089 $(mg/kg/day)^{-1}$ and the anticipated residue contribution, the upper bound cancer risk estimate for the U.S. population is 6.2×10^{-5}, contributed through all the published tolerances for ethalfluralin. As stated above, the Agency is requiring revocation of the tolerances for meat, milk, poultry, and eggs due to the presumption that there are undetectable, finite residues in these food items. When the cancer risk is calculated without these commodities' tolerances the resulting upper

bound risk is **5.7 x 10^{-7}**, a negligible risk. Of all the ethalfluralin commodities, cucurbits contribute the most ethalfluralin residues to the dietary exposure and risk. Cucurbits contribute 4.8 x 10^{-7} to the risk estimate of 5.7 x 10^{-7} given above. The resulting upper bound carcinogenic risk, excluding cucurbits, would be 8.8 x 10^{-8}.

b. Occupational and Residential

Worker carcinogenic risk for commercial M/L/A is in the range of 7 x 10^{-8} to 1 x 10^{-5} as noted in Table 3 above. The worst case scenario is for the commercial M/L using the liquid/dry flowable formulation with ground application equipment. These workers are estimated to have an extra cancer risk of 1 x 10^{-5}. Exposure assessments for all other mixer/loader/applicator scenarios resulted in upper bound risks of 1 x 10^{-6} to 7 x 10^{-8}, which are considered negligible.

Worker risks were calculated as follows:

Daily Dermal Dose (mg/kg/day) = (Exposure (mg/lb ai) x Max. Appl. Rate (lb ai/cycle) x Max. Treated)/70 kg

LADD (mg/kg/day) = Daily Dermal Dose (mg/kg/day) x (10 Work Days Per Yr/365 Days Per Year) x (35 Yrs/70 Yrs) x 0.028 (dermal absorption)

Commercial applicator is defined as an intermediate exposed individual (i.e., 10 days per year handling ethalfluralin).

Risk = Dermal LADD (mg/kg/day) x Q_1*

Contributions from inhalation exposure were not included in the cancer risk assessment because this exposure is considered to be significantly less than estimated dermal exposure. Inhalation exposure would not significantly increase the risk estimates. Therefore, no adjustment has been made to simulate workers wearing dust/mist respirators.

C. Environmental Assessment

1. Environmental Fate

All laboratory environmental fate data requirements necessary to support the reregistration of ethalfluralin for the uses set forth in this RED have been satisfied. While the Agency has identified deficienies in some studies, as discussed below, i.e., photodegradation on soil and soil mobility, they provide enough information for an overall assessment of the degradation, mobility or accumulation of ethalfluralin in the

environment. The Agency, therefore, has sufficient information at this time to provide an overall qualitative assessment for ethalfluralin.

a. Environmental Chemistry, Fate and Transport

Hydrolysis (GDLN 161-1)

Ethalfluralin is stable to hydrolysis at pH 3, 6, and 9. (MRID 00094805)

Photodegradation in water (GDLN 161-2)

Ethalfluralin in pH 5 buffer solution had a photodegradation half-life of 6.3 hours. Ethalfluralin did not degrade in the dark controls. The major photodegradate was identified by TLC as s-trifluoromethyl-3-nitro-1,2-benzendiamine (LY-50030; 24.4% applied). Three other compounds were isolated at $\leq$ 11.36% of applied. Seven unidentified photodegradates were also detected. (MRID 41613916)

Photodegradation on soil (GDLN 161-3)

Ethalfluralin in sandy loam soil had a photodegradation half-life of 14.23 days. Photodegradates were tentatively identified as s-trifluoromethyl-3-nitro-1,2-benzendiamine (LY-50030), 2-(1-methylethenyl)-4-nitro-6-trifluoromethyl-1H-benzimidazole (LY-275133), and 2-methyl-7-nitro-5-trifluoromethyl-1H-benzimidazole-3-oxide (LY-65138), all at maximums of $\geq$ 4.3%.

There was a problem with the dark control samples in this study. Approximately 50% of the applied radioactivity volatilized from the dark control samples incubated 30 days while no radioactivity volatilized from the exposed samples. The registrant stated that this volatile radioactivity was assumed to be ethalfluralin since "there was no such trapping in the exposed system". However, there was significant radioactivity evolved from the dark controls before the half-life of ethalfluralin in the exposed system. (MRID 41613917)

Aerobic soil metabolism (GDLN 162-1)

Ethalfluralin in sandy loam soil had a metabolism half-life of 46 days. Parent ethalfluralin decreased from 84.4% immediately posttreatment, 49% at 0.9 months and finally to 1.3% of the

applied radioactivity at 9 months. Radiolabelled degradates were identified ET-2E, ET-2M, ET-4, ET17E, ET20, ET28E, and M1 all at maximums ranging from 0.2-3.2% of applied radioactivity at various sampling intervals.

Ethalfluralin degradation appeared to be dependent on microbial-mediated processes with subsequent residue incorporation into nonlabile soil organic matter. (MRID 41613918)

Anaerobic soil metabolism (GDLN 162-2)

Ethalfluralin in sandy loam soil had a metabolism half-life of 13.8 days; ethalfluralin declined from 65% of applied radioactivity at the initiation of anaerobic conditions to 10% after 30 days of anaerobic incubation. Radiolabelled residues formed mainly during aerobic incubation were identified as ET-2M, ET2E, ET-15M, ET-17E, and ET-20 all recovered at $\leq$ 0.047 ppm ethalfluralin equivalents. During anaerobic incubation three main degradates were formed with maximum concentrations after 30 days of anaerobic incubation: ET-4 (0.119 ppm), M1 (0.074 ppm) and M2 (0.076 ppm). Other minor degradates at maximums of $\leq$ 0.017 ppm were ET-13E, ET-3, ET-5E, and ET-7. Ethalfluralin degradation appeared to be dependent on microbial-mediated processes with subsequent residue incorporation into nonlabile soil organic matter. (MRID 41613919)

Anaerobic aquatic metabolism (GDLN 162-3)

The calculated anaerobic aquatic half-life of ethalfluralin was approximately 38 hours. These data do not fulfill the anaerobic aquatic metabolism data requirement because the day 0 samples were not extracted "for several hours" and 90% of the applied ethalfluralin had degraded prior to the extraction. This study does not need to be repeated, however, because the acceptable anaerobic soil metabolism study will fulfill these data requirements.

Mobility Studies

Soil mobility (Batch Equilibrium: 163-1)

The reported data indicate ethalfluralin should be immobile in soil. Ethalfluralin has a high binding affinity on soil. Freundlich adsorption coefficients were 11.9 ml/g in sand, 32.6 ml/g in sandy loam soil, 53.0 ml/g in loam soil, and 97.0 ml/g in clay loam soil; slopes were 0.954-0.984. Average (non-Freundlich) desorption

coefficients ranged from 16.2 to 20.9 ml/g in sand, 46.7 to 66.8 ml/g in sandy loam, 71 to 117.3 ml/g in loam, and 118.6 to 146.3 ml/g in clay loam soil.

Mobility (Aged Soil Column Leaching: 163-1)

Ethalfluralin residues appear to be relatively immobile in soil. The majority of radiolabelled residues (77% of applied) were detected in surface 6 cm of soil. However, a small percentage of radiolabelled residue was detected (< 7% of applied) in leachate samples. The mobile residue was tentatively identified as ET-20. The study provides supplemental data on mobility of "aged" ethalfluralin residues. The data are supplemental because of insufficient data on the identification of mobile degradates. The study may satisfy the aged residue portion of the 163-1 data requirement with submission of a complete explanation on the identification of residues in leachate and soil samples. (MRID 41890102)

Mobility (Laboratory Volatility: 163-2)

The reported data indicate that volatilization of ethalfluralin and its degradates should not be a major route of dissipation. Radiolabelled residues volatilized (< 5% of applied ethalfluralin) from sandy loam soil. Volatility rates of radiolabelled residue (presumably ethalfluralin) from soil ranged from 5.65×10^{-4} to 1.96×10^{-2} ug/cm^2/hr.

The study is only marginally acceptable because volatile residues were not analyzed, but were assumed to be parent ethalfluralin. Because ethalfluralin and its degradates are not very volatile from soil, the Agency believes that additional data on the volatility of ethalfluralin are not needed at this time. (MRID 42496601)

Terrestrial field dissipation

When applied at 1.5 lb ai/A and incorporated to bare ground, ethalfluralin dissipated from an uncropped silty clay loam soil in Illinois with a calculated half-life of 23 days. Ethalfluralin dissipated probably by microbially mediated degradation from an uncropped sandy loam soil in Georgia with a calculated half-life of 28 days when applied at 1.3 lb ai/A and incorporated. Only "ethalfluralin residues" were analyzed because there were no major

degradates of ethalfluralin; the compound splits into numerous smaller compounds. Ethalfluralin did not leach below the 6-inch layer at any sampling interval from either site. (MRIDs 41978101; 41613920)

Fish Bioaccumulation

Ethalfluralin accumulated in rainbow trout tissues when the fish were incubated in flow through systems at 0.86 ng/mL for 28 days; bioconcentration factors were 1520x for edible tissues, 860x for nonedible tissues, and 1180X for whole fish samples. Ethalfluralin also depurated rapidly with an elimination half-life of approximately 3 days when fish were held in flow-through tanks containing pesticide-free water. (MRID 41994902)

Surface Water Data

The Agency has no data on the concentrations of ethalfluralin in surface waters, and has not generated Estimated Environmental Concentrations (EEC's) beyond those at the screening level for use in the aquatic risk assessments. However, ethalfluralin can contaminate surface water through spray drift from ground spray application. Substantial quantities of ethalfluralin could also be available for runoff for several weeks post-application (aerobic soil metabolism half-life of 46 days; terrestrial field dissipation half-lives of 23 and 28 days). However, the frequent incorporation into soil should limit the amount applied that is available for runoff. Although ethalfluralin may be moderately susceptible to photodegradation on soil, its frequent incorporation into soil should also limit its exposure to sunlight. The relatively high soil/water partitioning of ethalfluralin (Freundlich adsorption binding constants of 12, 33, 53, and 97; K_{oc}s of 4103, 3976, 5000, and 8220) indicates that a large fraction of any ethalfluralin runoff will be via adsorption to eroding soil. However, a significant fraction may sometimes occur via dissolution in runoff water from the lower binding soils when high runoff water to sediment yield ratios occur.

The persistence of ethalfluralin in surface water should be limited by its susceptibility to rapid direct photolysis in water (half-life of 6 hours), particularly in clear shallow water. Its rapid anaerobic degradation (anaerobic aquatic half-life of 38 hours), should also limit its persistence in anaerobic water and sediment. However, its stability to abiotic hydrolysis coupled with only a

moderate susceptibility to aerobic degradation indicate that it will be somewhat more persistent in aerobic waters with higher light attenuation, low microbiological activities, and high hydrological residence times. Its relatively high soil/water partitioning indicates that much of the ethalfluralin in surface waters will be adsorbed to suspended and bottom sediment. Ethalfluralin has a moderate potential for bioaccumulation bioconcentration factor = 860X - 1520X.

Groundwater Data

From the environmental fate data provided, the Agency would not predict ethalfluralin to be a groundwater contaminant. There are no records of detections of this chemical in groundwater. A chemically and structurally similar compound, trifluralin (K_{ads} 55-156 mL/g) has been detected in the groundwater in 10 of 21 states from 58 of 5590 wells tested. However, the Agency concluded that no groundwater label advisory or management plan was necessary for trifluralin since these detections were mostly either unconfirmed analytically, from very shallow ground water, or at very low levels. Because these two compounds are similar in structure and fate parameters, the Agency concludes that ethalfluralin is not expected to be a groundwater contaminant.

b. Environmental Fate Assessment

The data submitted to support ethalfluralin reregistration are not complete, but provide sufficient information for a qualitative environmental fate assessment. Based on laboratory studies, ethalfluralin is expected to dissipate by binding to soil particles and then degrading both aerobically and anaerobically. Freundlich K_{ads} values ranged from 12 to 97 mL/g and in the field ethalfluralin did not leach. Laboratory metabolism half-lives in soil were 46 days for aerobic systems and 14 days for anaerobic systems; field half-lives ranged 23-51 days.

There are several minor metabolites of ethalfluralin in soil systems, but no major metabolites were recovered. Some minor metabolites appeared to be mobile in column leaching studies.

Ethalfluralin is not expected to be a groundwater contaminant, but there is some potential for ethalfluralin to reach surface waters on eroded soil particles. In surface waters ethalfluralin would be expected to photodegrade (laboratory half-life of 6 hours) and to degrade rapidly in anaerobic sediments possibly by electrochemical reactions (anaerobic

aquatic half-life of 38 hours). Ethalfluralin was not volatile in the laboratory; however, no assessment of spray drift potential is possible from the submitted data.

From the environmental fate data provided, the Agency would not predict ethalfluralin to be a groundwater contaminant. However, a structurally similar compound, trifluralin, has been detected in the groundwater in 10 of 21 states. Since these two compounds are so similar in structure and fate parameters, the Agency cannot make a more complete assessment regarding ethalfluralin in groundwater until the groundwater assessment of trifluralin is finished.

2. Ecological Effects

All ecological effects data requirements necessary to support the reregistration of ethalfluralin for the uses set forth in this RED have been satisfied. The Agency, therefore, has sufficient information at this time to provide an overall qualitative assessment for ethalfluralin.

a. Ecological Effects Data

The ecotoxicological data base is adequate to characterize the toxicity of ethalfluralin to nontarget terrestrial and aquatic organisms when used on the terrestrial food and feed and nonfood sites specified in this document.

(1) Terrestrial Data

In order to establish the toxicity of ethalfluralin to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail or ring-necked pheasant).

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure.

(a) Avian Acute Toxicity

Technical ethalfluralin (94.5%) is considered to be practically nontoxic to bobwhite quail with an acute oral LD_{50} of greater than 2,000 ppm. The guideline requirement for the avian acute oral LD_{50} study is fulfilled. (MRID 070677)

(b) Avian Subacute Dietary Toxicity

On a subacute dietary basis, ethalfluralin (94.5%) is considered to be practically nontoxic to bobwhite quail and mallard ducks with dietary LC_{50}'s of greater than 5,000 ppm. (MRID 070677)

(c) Avian Reproduction

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Ethalfluralin is a persistent chemical (half-life ranging from 14 to 60 days) that is applied immediately preceding and/or during the breeding season. Two avian reproduction studies, one with a species of waterfowl, preferably the mallard, and one with a species of upland gamebird, preferably the bobwhite quail, are required for the technical material.

In two avian reproduction studies, there were no adverse effects at 1,000 ppm, the highest dietary intake tested, from ethalfluralin (93.5%) in the bobwhite quail or the mallard duck. A Lowest Observed Effect Level (LOEL) could not be determined. The guideline requirements (71-4a,b) for avian reproductive testing are fulfilled. (MRID 070677)

(d) Toxicity to Nontarget Mammals

Oral and dermal LD50 values for ethalfluralin end-use product formulations were obtained from data submitted to the Agency and are tabulated below for the laboratory rat.

Table 5.

Mammalian Acute Oral Toxicity Findings			
Species	**% A.I.**	**LD50(mg/kg) Oral**	**LD50(mg/kg) Dermal**
Rat, small mammal	35.5%[a]	> 509, < 5,092	> 5,092
"	50% dry flowable	> 5,000	> 2,000
"	10%[a]	> 5,000	> 2,000
"	10% granules	> 5,000	> 5,000

[a] Formulation type unknown

The available mammalian data indicate that ethalfluralin end-use product formulations are slightly toxic to practically nontoxic to small mammals on an acute oral and dermal basis.

(2) Aquatic Data

(a) Freshwater Fish Toxicity

Acute toxicity - technical ethalfluralin

The minimum data required to evaluate the acute toxicity of ethalfluralin to freshwater fish are two 96-hour LC_{50} freshwater fish toxicity tests using the technical material. One test (72-1a) is for warm-water fish, preferably bluegill sunfish, and the other (72-1c) is for a cold-water fish, preferably rainbow trout. The acute toxicity studies for freshwater fish are summarized below.

Table 6.

Freshwater Fish Acute Toxicity Findings (Technical)				
Species	**%ai**	**LC50 (ppb)**	**MRID Number**	**Conclusion**
Rainbow trout	100	37	070677	very highly toxic
	95.46	130	41613903	highly toxic
Bluegill sunfish	100	32	070677	very highly toxic
	95.66	100	41613902	highly toxic
Goldfish	100	260	070677[a]	highly toxic

[a] Not a guideline study due to use of goldfish as the test species.

The guideline requirements for acute toxicity testing of technical ethalfluralin with warmwater fish (72-1a) and coldwater fish (72-1c) are fulfilled. The data indicate that technical ethalfluralin is highly to very highly toxic to rainbow trout and bluegill sunfish.

Acute toxicity - formulated ethalfluralin

An acute test with bluegill sunfish is required for the formulated product, which contains an inert ingredient that may affect toxicity.

The formulated product of ethalfluralin (36.5%) is considered to be highly toxic to bluegill sunfish with a product LC_{50} of 210 ppb. The guideline requirement (72-1b) for an acute fish toxicity test with the formulated product is fulfilled. (MRID 42176401)

Sediment study

An acute toxicity sediment study was submitted, because ethalfluralin persists in soils and is very highly toxic to fish. Ethalfluralin (29.9%) was mixed in soil at 1, 10, and 100 ppm; 15-g and 50-g soil samples from each concentration were added to separate 15-l water chambers in which 20 bluegill sunfish (2 replicates of 10 fish each) were exposed. Fifteen grams of soil in

15 liters of water was used to represent an amount that could conceivably erode from a treated field; 50 g in 15 l of water provided a limit of turbidity that still permitted observations of the test fish. The concentration of ethalfluralin in the water was measured when fish were added to the chambers and after 96 hours. The results of this study are summarized below.

Table 7.

Amount of ai in soil (ppm)	Amount of soil (g)	ai conc. in water (ppb)		Mortality
		initial (0 hrs)	final (96 hrs)	
1	15	< 1	< 1	1 (5%)
	50	nr[1]	< 1	0
10	15	6	< 1	0
	50	17	< 1	0
100	15	58	1	11 (55%)
	50	85	8.5	20 (100%)

These data indicate that ethalfluralin released from soil sediments can be lethal to sunfish (0-55% mortality) when concentrations in the aqueous phase reach approximately between 17 and 58 ppb. (MRID 070677)

Chronic Toxicity - technical ethalfluralin

A fish early life stage toxicity test is required, because the acute toxicity of ethalfluralin to daphnids is less than 1 ppm as discussed below in part (b). The chronic fish toxicity study is summarized below.

Table 8.

Fish Early Life Cyle Toxicity Findings (Technical)				
Species	**%ai**	**Results (µg/l)**	**MRID Number**	**Conclusion**
Rainbow trout	95.6	NOEL = 0.4 LOEL = 1.4 MATC[1] = 0.7	41994901	See Discussion

[1] Maximum Allowable Toxic Concentration (geometric mean)

The guideline requirement (72-4a) for an early life stage toxicity test with freshwater fish is fulfilled. The most sensitive parameters affected in trout were larval length and weight.

(b) Freshwater Invertebrate Toxicity

Acute Toxicity - technical ethalfluralin

The minimum data requirement to establish acute toxicity to freshwater invertebrates is a 48-hour acute study with the technical material. Test organisms should be first instar *Daphnia magna* or early instar amphipods, stoneflies, or mayflies.

Technical ethalfluralin (94%) is considered to be very highly toxic to *Daphnia magna* with an EC_{50} of 60 ppb. The guideline requirement for an acute toxicity study with freshwater invertebrates (72-2) is satisfied. (MRID 070677)

Acute toxicity - formulated ethalfluralin

Acute toxicity testing with formulated ethalfluralin is required because an end-use product contains an inert that may affect toxicity.

The formulated product with ethalfluralin (36.5%) is considered to be slightly toxic to *Daphnia magna* with a product EC_{50} of 18.1 ppm. The guideline requirement (72-2b) for an acute invertebrate toxicity study with the formulated product is fulfilled. (MRID 42176402)

Freshwater invertebrate life cycle - technical ethalfluralin

A freshwater invertebrate life cycle toxicity test is required, because the acute toxicity to daphnids is less than 1 ppm. The chronic toxicity studies with an aquatic invertebrate are summarized below:

Table 9.

Freshwater Invertebrate Life Cycle Toxicity Findings				
Species	**%ai**	**Results (µg/l)**	**MRID No.**	**Conclusion**
Daphnia magna	95.6	NOEL = 67 LOEL = 162 MATC[2] = 105	41613907[1]	See Discussion
	95.9	NOEL = 24 LOEL = 37 MATC[2] = 30	42930101	See Discussion

[1] reproduction was highly variable in all 5 test concentrations
[2] Maximum Allowable Toxicant Concentration (geometric mean)

The guideline requirement (72-4b) for a life cycle toxicity test with an aquatic invertebrate is fulfilled. Reproduction was the most sensitive parameter affected in daphnids.

(c) Estuarine/Marine Toxicity

Acute Toxicity

Acute toxicity testing with marine/estuarine organisms is required for ethalfluralin because of the soybean use pattern. The acute toxicity studies for marine/estuarine organisms are summarized below:

Table 10.

Estuarine/Marine Acute Toxicity Findings				
Species	**%ai**	**LC50 (ppb)**	**MRID Number**	**Conclusion**
Sheeps-head	95.46	240	41613904	Highly Toxic
Eastern oyster	95.46	100	41613905[1]	Highly Toxic
	95.93	170	42889801	
Mysid shrimp	95.46	230	41613906	Highly Toxic

[1] shell deposition by control oysters did not meet the minimum growth standard of 2.0 mm

The guideline requirement for acute toxicity studies with marine/estuarine fish (72-3a), mollusks (72-3b) and shrimp (72-3c) are satisfied. These data indicate that technical ethalfluralin is highly toxic to sheepshead minnows, oysters, and shrimp.

(3) Non-Target Insects Data

The minimum data required to establish the acute toxicity to *Apis mellifera*, honey bees, is an acute contact LD_{50} study with the technical material.

Ethalflurlin (95%) is considered to be practically nontoxic to honey bees with a LD_{50} of 51 ug/bee. The guideline requirement is fulfilled. (MRID 41613914)

(4) Non-Target Plants Data

Terrestrial Plants - technical ethalfluralin

Terrestrial plant testing (seed germination, seedling emergence and vegetative vigor) is required for herbicides which have terrestrial nonfood/feed or aquatic nonfood (except residential) use patterns and which have endangered or threatened plant species associated with the site of application. In addition, these tests are required for ethalfluralin, because the vapor pressure of the technical-grade material exceeds 1.0×10^{-5}mm Hg at 25°C and not all end-use products are incorporated immediately after application. The acceptable Tier I and II phytotoxicity studies are summarized below.

Table 11.

Nontarget Terrestrial Plant Toxicity Findings				
Test	**% ai**	**Results[1] (lbs ai/acre)**	**MRID Number**	**Conclusion**
Seed germination	95.6	NOEC < 1.69[2]	41613911	See Below
Seedling emergence	95.6	$EC_{25} = 0.10$[3]	41613913	See Below
Vegetative vigor	95.5	$EC_{25} = 0.31$[4]	42904201	See Below

[1] values are for the most sensitive of the 10 species tested (cabbage, corn, cotton, cucumber, onion, radish, sorghum, soybean, sunflower, and wheat)

[2] radicle length (cabbage and wheat) was the parameter affected

[3] the parameters affected were plant height (sorghum) and plant weight (wheat)

[4] the parameter affected was shoot dry weight (cotton)

Tier I and II terrestrial plant testing is complete. The guideline requirement (122-1) for seed germination/ seedling emergence/vegetative vigor is satisfied.

Aquatic plants - technical ethalfluralin

Aquatic plant growth studies are required for all herbicides for which the solubility exceeds 10 ppm. Because the solubility of ethalfluralin in water is less than 1 ppm, these studies are not required. However, one acceptable study has been submitted. Ethalfluralin (95.6%) has an EC_{50} of 25 µg/l. This indicates an increasing inhibition of growth and reproduction in *Selenastrum capricornutum* by increasing amounts of ethalfluralin. (MRID No. 41613912) This study is scientifically sound but is not a guideline requirement.

b. Ecological Effects Risk Assessment

(1) Risk to Terrestrial Animals

Acute risks/spray applications

Wildlife may be exposed to ethalfluralin either by consuming contaminated food items (e.g., seeds, fruits, insects) or by directly ingesting granules. Contamination of vegetation is not likely to pose a high risk within fields, because ethalfluralin is applied before grasses and broadleaf weeds emerge. However, some exposure might occur along field borders in some situations. Birds also might be exposed to ethalfluralin by ingesting granules as a source of grit.

The criterion for the determination of hazard and presumption of unacceptable risk from exposure for acute avian and mammalian species is a value greater than or equal to 0.5 for the quotient of the preliminary estimated environmental concentration (EEC) divided by the lowest LD_{50} value for birds and mammals--this is known as the risk quotient (RQ).

Acute and Dietary RQ = EEC/LD_{50} or
EEC/LC_{50} > or = 0.5 for birds and mammals

(a) Avian Acute Oral and Subacute Dietary Effects

Actual residue data on potential food items of birds are not available for ethalfluralin. Based on maximum application rates, however, estimates of expected terrestrial residues (EECs) from spray applications can be calculated according to Hoerger and Kenaga (1972). The residues tabulated below are the highest to be expected from single maximum applications of 1.7 and 1.3 lbs ai/acre, the two highest application rates for ethalfluralin.

Table 12.

Item	EEC (ppm)	
	1.7 lbs ai/acre[1]	1.3 lbs ai/acre[2]
Short grasses	408	312
Tall grasses	187	143
Leaves, Leafy crops	212	163
Forage and small insects	99	75
Seed pods and large insects	20	16
Seeds	17	13
Fruits	12	9

[1] sites: alfalfa, dry beans, cucumbers, melons, pumpkins, squash, watermelons
[2] site: soybeans

Once the EECs have been estimated for the various application rates on potential food items, acute Risk Quotient (RQ) values can be determined as follows:

$$RQ = EEC/LC_{50}$$

RQ values are then compared to the acute Levels of Concern (LOCs):

High Risk (HR) ≥ 0.5
Restricted Use (RU) ≥ 0.2
Endangered Species (ES) ≥ 0.1

where HR = high acute risk
RU = risk that may be mitigated by restricted use
ES = endangered species may be affected

However, all acute LOCs are assumed to be ≥ 1 when the LC_{50} values are > 5000 ppm with no treatment-related mortality at that level.

Acute RQ values for the two highest application rates, based on the highest residue expected (short grasses), are tabulated below for birds.

Table 13.

Appl. rate (lbs ai/acre)	EEC (ppm)	Risk Quotient (EEC/LC_{50})	Acute LOC
1.7[1]	408	0.08	Risk ≥ 1[3]
1.3[2]	312	0.06	

[1] sites: alfalfa, dry beans, cucumbers, melons, pumpkins, squash, watermelons

[2] site: soybeans

[3] The LOC for High Risk, Restricted Use, and Endangered Species is ≥ 1, because the LC_{50} values were > 5000 ppm with no dose-related mortality.

The RQ values are far less than the acute LOC. Therefore, no acute risks to endangered and nonendangered bird species are presumed. RQ values based on residue levels on other potential avian food items (seeds, insects, fruits) would be even less than those tabulated above for short grasses. Because there is no presumed risk at application rates of 1.7 or 1.3 lbs ai/acre, none is expected at the lower application rates (0.75-1.15 lbs ai/acre).

Acute risks/granular applications

RQ values for granular applications are based on the number of $LD_{50}s/ft^2$. The acute LOC values are the same as those cited for spray applications. The LD_{50}/ft^2 is determined as follows:

$$LD_{50}/ft^2 = \text{mg ai}/ft^2 \div (LD_{50} \times \text{bird wt.})$$

where

$$\text{mg ai}/ft^2 = \text{lbs ai/acre applied} \times 453{,}590 \text{ mg/lb} \div 43{,}560\ ft^2/\text{acre}$$

For a broadcast granular application that is incorporated, incorporation efficiency is assumed to be 85% (EPA 1992); therefore, 15% of the granules applied are assumed to remain on the soil surface. For the bobwhite quail, RQ values are tabulated below for both unincorporated and incorporated applications at the maximum application rate of 1.7 lbs ai/acre.

Table 14.

Bobwhite quail body wt. (g)[1]	RQ ($LD_{50}s/ft^2$)		LOC
	Uninc. appl.	Inc. appl.	
170	< 0.052	< 0.008	Risk > 1[2]

[1] body weight was obtained from Urban and Cook (1986)

[2] The LOC for High Risk, Restricted Use, and Endangered Species is ≥ 1, because the LC_{50} values were > 5000 ppm with no dose-related mortality.

The RQ values tabulated above for bobwhite quail do not exceed the acute LOC for birds. Therefore, no undue risk to avian species is presumed from granular applications of ethalfluralin at the present use rates.

(b) Avian Chronic Effects

Based on expected residue levels and results of avian reproductive testing, chronic risks to birds would not be expected. Ethalfluralin is applied only once per season. The maximum expected residue (408 ppm on short grasses) from a single application is well below the reproductive-effects NOEL of > 1000 ppm dietary intake. The RQ for chronic exposure is calculated as EEC/NOEL; if the RQ ≥ 1, the chronic LOC, a chronic risk is presumed. For ethalfluralin, 408/1000 = 0.4; therefore, no chronic risk is presumed based on avian reproduction.

(c) Mammalian Acute Oral and Subacute Dietary Effects

Oral and dermal LD_{50} values for ethalfluralin end use product formulations were obtained from data submitted to the Agency and were tabulated above (Table 5) for the laboratory rat. These values (> 509 to < 5092 mg/kg for oral LD_{50}s and > 2000 to > 5092 mg/kg for dermal LD_{50}s) classify formulated ethalfluralin as slightly toxic to practically nontoxic to laboratory rats on an acute oral and dermal basis. Based on these toxicity data, low application rates and resulting residues on vegetation and insects, lack of food and cover in fields at treatment time (i.e., prior to

emergence of any vegetation), and incorporation of granules, minimal risk to mammals is anticipated from the present uses of ethalfluralin.

(2) Risk to Aquatic Animals

Ground applications of ethalfluralin could result in a potential risk to aquatic organisms from runoff and drift of active ingredient. Aquatic residues in ponded waters were estimated from the Agency's Tier I program. This program calculates instantaneous loading in a 6-ft. deep, 1-acre pond within a 10-acre drainage basin and estimates average residue levels after 4, 21, and 56 days. Residues are based on application rate, environmental fate data (solubility, KOC value, aerobic soil metabolism, hydrolysis, photolysis) and depth of pesticide incorporation. The table below provides predicted aquatic residues for applications at the maximum rate of 1.7 lbs ai/acre.

Table 15.

Type of appl.	Predicted aquatic residues (ppb)			
	Instantaneous	**4-day avg.**	**21-dayavg.**	**56-day avg.**
unincorporated spray[1]	7.37	3.78	0.80	0.30
incorporatedspray[2]	1.96	1.03	0.22	0.08
incorporated granules[3]	1.82	0.93	0.20	0.07

[1] sites: cucumbers, melons, pumpkins, squash, watermelons
[2] sites: alfalfa, dry beans
[3] site: dry beans

LOCs and RQ values for aquatic organisms are tabulated below for incorporated and unincorporated applications of ethalfluralin.

Table 16.

Aquatic organism	RQ (EEC/LC_{50} or EC_{50})			Acute LOC
	Inc. granules	Inc. spray	Uninc. spray	
Freshwater fish	0.06	0.06	0.23	HR $\geq$ 0.5 RU $\geq$ 0.1 ES $\geq$ 0.05
Daphnia magna	0.03	0.03	0.12	
Marine/estuarine fish	< 0.01	0.01	0.03	
Marine/estuarine invertebrates	0.02	0.02	0.07	

Based on these RQ values, high acute risk to aquatic organisms is not anticipated. However, the restricted use trigger has been exceeded for freshwater organisms from an unincorporated application at the present label rate of 1.7 lbs. a.i./acre. Endangered species triggers have been exceeded for freshwater organisms and estuarine/marine invertebrates.

Chronic risks to aquatic organisms are assessed by comparing 21-day and 56-day average aquatic residues to MATC values for daphnids (30 ppb) and fish (0.7 ppb), respectively. The chronic LOC for aquatic organisms is $\geq$ 1. RQ values for spray and granular applications at the maximum rate of 1.7 lbs ai/acre are tabulated below. Based on these values, no chronic risks are presumed.

Table 17.

Species	RQ (EEC[1]/MATC)			Chronic LOC
	Inc. granules	Inc. spray	Uninc. spray	
Rainbow trout	0.1	0.1	0.4	$\geq$ 1
Daphnia magna	< 0.1	< 0.1	< 0.1	

[1] the EEC for fish is based on the 56-day average residue level, whereas for daphnids the 21-day average is assumed.

(3) Risk to Terrestrial, Semi-Aquatic and Aquatic Plants

(a) Nontarget Terrestrial and Semi-Aquatic Plant Effects

Risk to terrestrial plants is assessed by comparing phytoxicity LOCs to runoff of ethalfluralin expected from maximum applications. Risk is assessed to plants inhabiting areas adjacent to treated sites and to plants growing in wetter areas (i.e., semi-aquatic terrestrial species) farther away where channelized runoff waters may collect. A level of concern exists for both endangered and nonendangered terrestrial plants if runoff exceeds the nontarget-plant EC_{25} values for seed germination and seedling emergence test results.

At maximum ground-application rates of 1.7 lbs ai/acre and anticipated 1% runoff of active ingredient, runoff onto areas adjacent to treated sites is expected to be about 0.02 and 0.003 lbs ai/acre for unincorporated and incorporated applications, respectively (see table below). The RQs are less than 1 for both methods of application, indicating minimal risk to nontarget plants inhabiting dry areas adjacent to treated fields. RQs from application rates of 1.3, 1.1, and 0.75 lbs ai/acre would be even less than those tabulated.

Table 18.

Type of appl.	Appl. rate[1]	EEC[1] near site	RQ[2]	EEC[1] away from site	RQ[2]
Unincorporated[3]	1.7	0.02	0.2	0.17	1.7
Incorporated[4]	1.7	0.003	0.03	0.034	0.34

[1] lbs ai/acre

[2] Risk Quotient (RQ) = EEC/EC_{25}, where the EC_{25} = 0.1 lbs ai/acre [seedling emergence (sorghum, wheat)]

[3] sites: cucumbers, melons, pumpkins, squash, watermelons

[4] sites: alfalfa, dry beans

Runoff onto wet areas (i.e., moist, saturated, or flooded soils) away from treated sites is expected to be about 0.17 lbs ai/acre for an unincorporated application. The resulting RQ of 1.7 indicates some risk to semi-aquatic terrestrial plants in the vicinity of treated fields (cucumbers, melons, pumpkins, squash, and watermelons). No risk to such plants is anticipated from incorporated applications.

(b) Nontarget Aquatic Plant Effects

The EC_{50} value for *Selanastrum capricornutum* is 20 ppb. Expected aquatic residues (1.82-7.37ppb) for a 6-ft. deep pond do not exceed this LOC; therefore, high risk is not expected.

(4) Risk to Endangered Species

For endangered avian and mammalian species the risk quotient is a value greater than or equal to 0.1. For endangered aquatic vertebrate and invertebrate species, the risk quotient is 0.05.

$RQ = EEC/LC_{50} > or = 0.1$ for endangered birds and mammals,

the

$RQ = EEC/LC_{50} > or = 0.05$ for endangered aquatic animals

and the

$RQ = EEC/EC_{25}$ and the $EEC/EC_{50} > or = 1$ for terrestrial, semi-aquatic and aquatic plants.

Endangered species acute LOCs have been exceeded for freshwater organisms and estuarine/marine invertebrates from unincorporated applications, for freshwater fish from incorporated applications, and for plants growing in wet areas receiving channelized runoff from treated sites (unincorporated treatments only).

IV. Risk Management and Reregistration Decision

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing ethalfluralin active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing ethalfluralin except those labeled for postemergence and posttransplant applications to cucurbits. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of ethalfluralin, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of ethalfluralin and to determine that ethalfluralin, as stipulated in this document, can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing ethalfluralin except for those labeled for postemergence and posttransplant applications to cucurbits as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of ethalfluralin, except those noted above, are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing ethalfluralin, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients ethalfluralin, the Agency has sufficient information on the health effects of ethalfluralin and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing ethalfluralin for all uses with the exception of the postemergence and posttransplant uses on cucurbits are eligible for reregistration. The Agency has determined that ethalfluralin products, labeled and used as specified in this Reregistration Eligibility Decision document, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of ethalfluralin except those labeled for postemergence and posttransplant applications to cucurbits are eligible for reregistration. The studies supporting these uses are currently being reviewed by the Agency. Upon review and acceptance of these data, the Agency will consider the uses eligible and will proceed with reregistration of products labeled for these uses.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for ethalfluralin. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.416:

The qualitative nature of the residue in beans and peanuts is tentatively understood pending submission of additional confirmatory data. The tentative terminal residue of concern in plants is ethalfluralin *per se*; the current tolerance expression for plants is adequate. However, before plant metabolism may be considered fully understood, an acceptable confirmatory cucurbit metabolism study must be submitted.

The tolerances listed in 40 CFR §180.416 are for residues of ethalfluralin *per se*. All tolerances are established at 0.05 ppm. Adequate enforcement methods are available for the determination of ethalfluralin residues in/on plant and animal commodities. Adequate field residue studies are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.416 for beans (dry), peanuts, peas (dry), soybean, and sunflower seed. Additional confirmatory data are required for the postplant-preemergence application use on cucurbits (cucumbers, melons, and squash) before the adequacy of the established tolerance for cucurbit vegetables group may be reassessed. New data are also required for the postemergence and posttransplant application to cucurbits. These data are not considered confirmatory since the Agency lacks data which would allow an interim assessment of the residues.

Adequate processing studies have been conducted on peanuts, soybean, and sunflower seed. No food or feed additive tolerances are established or required.

The qualitative nature of the residue in animals is adequately understood based on acceptable poultry and ruminant metabolism studies. The residue of concern in milk, eggs, and animal tissues is ethalfluralin *per se*. As a result of the exaggerated feeding levels (200x), the requirements for animal feeding studies were waived. It was also concluded that residues of ethalfluralin from up to 10x dietary burden would not be quantifiable (< 0.05 ppm). Therefore, the existing tolerances for eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep should be revoked. A summary of ethalfluralin tolerance reassessments is presented in Table 19.

Anticipated Residues

Anticipated residues in the various raw agricultural commodities are given in Table 20. The calculations are based on the tolerance reassessments of Table 19 and percent crop treated data from the Agency.

Table 19. Tolerance Reassessment Summary for Ethalfluralin

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.416			
Beans, dry	0.05	0.05	--
Cattle, fat	0.05	Revoke	Not needed
Cattle, meat	0.05	Revoke	Not needed
Cattle, mbyp	0.05	Revoke	Not needed
Cucurbits vegetable group	0.05	Additional residue data required	*Cucurbit vegetables group*
Eggs	0.05	Revoke	Not needed
Goats, fat	0.05	Revoke	Not needed
Goats, meat	0.05	Revoke	Not needed
Goats, mbyp	0.05	Revoke	Not needed
Hogs, fat	0.05	Revoke	Not needed
Hogs, meat	0.05	Revoke	Not needed
Hogs, mbyp	0.05	Revoke	Not needed
Horses, fat	0.05	Revoke	Not needed
Horses, meat	0.05	Revoke	Not needed
Horses, mbyp	0.05	Revoke	Not needed
Milk	0.05	Revoke	Not needed
Peanuts	0.05	0.05	--
Peanuts hulls	0.05	0.05	*Peanuts, hulls*
Peas, dry	0.05	0.05	--
Poultry, fat	0.05	Revoke	Not needed
Poultry, meat	0.05	Revoke	Not needed
Poultry, mbyp	0.05	Revoke	Not needed
Sheep, fat	0.05	Revoke	Not needed
Sheep, meat	0.05	Revoke	Not needed
Sheep, mbyp	0.05	Revoke	Not needed
Soy beans	0.05	0.05	*Soybean*
Sunflower seed	0.05	0.05	--

Table 20: Anticipated Residues of Ethalfluralin in Plant and Animal Commodities

Commodity[1]	Reassesed Tolerance (ppm)	Field Trial Results (ppm)	Crop Treated (% Maximum)	Anticipated Residue[5] (ppm)
Beans, dry	0.05	< 0.01	50	0.01
Cattle, fat	N/A	-	-	0
Cattle, meat	N/A	-	-	0
Cattle, mbyp	N/A	-	-	0
Cucurbit vegetable group	0.05[2]	< 0.01[3]	100[4]	0.05[5]
Eggs	N/A	-	-	0
Goats, fat	N/A	-	-	0
Goats, meat	N/A	-	-	0
Goats, mbyp	N/A	-	-	0
Hogs, fat	N/A	-	-	0
Hogs, meat	N/A	-	-	0
Hogs, mbyp	N/A	-	-	0
Horses, fat	N/A	-	-	0
Horses, meat	N/A	-	-	0
Horses, mbyp	N/A	-	-	0
Milk	N/A	-	-	0
Peanuts	0.05	< 0.01	40	0.008
Peanut Hulls	0.05	< 0.01	40	0.008
Peas, dry	0.05	< 0.01	5	0.001
Poultry, fat	N/A	-	-	0
Poultry, meat	N/A	-	-	0
Poultry, mbyp	N/A	-	-	0
Sheep, fat	N/A	-	-	0
Sheep, meat	N/A	-	-	0
Sheep, mbyp	N/A	-	-	0
Soy beans	0.05	< 0.01	5	0.001
Sunflower seed	0.05	< 0.01	30	0.006

[1] The tolerance for the rac also applies to the processed commodities.

[2] No data to reevaluate tolerance. Existing tolerance is 0.05 ppm.

[3] Based on 1982 field trial data NOT submitted for reregistration purposes.

[4] Cantaloupes, 10%; cucumbers, 35%; honeydew, 10%; watermelon, 10%; pumpkin and squash, unknown.

[5] Anticipated Residue = (2 X Field Trial Concentration) X (% Crop Treated), except cucurbits. For cucurbits, anticipated residue = Tolerance = 0.05 ppm. The field trial concentration for all crops was < 0.01 ppm, the limit of detection (not the limit of quantitation), and 2 X 0.01 ppm was used to compensate for possible less than optimum instrument response and the resulting uncertainty in the limit of detection. A limit of quantitation of $\leq$ 0.05 ppm has been demonstrated for numerous commodities. The more conservative tolerance value (0.05 ppm) was used for cucurbits because field trial data are required.

CODEX HARMONIZATION

There are no Codex MRLs established or proposed for residues of ethalfluralin. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

2. Risk Mitigation Measures

Dietary and Occupational\Residential

Ethalfluralin is considered a possible (Group C - quantifiable) carcinogen and a developmental toxicant by the Agency based on the toxicology data discussed above. The Agency has considered dietary and occupational risks for these two endpoints. Dietary risks for carcinogenicity and developmental toxicity are considered negligible, especially if existing residue contributions from meat, milk, poultry, and eggs are excluded. Ethalfluralin tolerances for these commodities will be revoked for reasons explained earlier.

Likewise, the occupational risks of these two toxicological endpoints are low. The Agency believes risk of developmental toxicity to workers is negligible due to the low dermal absorption of this chemical. For carcinogenicity the estimated upper bound risks to these workers are as high as 1×10^{-5} for mixers and loaders of liquid/dry flowable formulations applied with ground equipment. Other worker scenarios have lower, negligible risks, equal to or less than 1×10^{-6}. These risk estimates assume workers wear coveralls over short pants and short shirt sleeves (single layer protection) and chemical resistant gloves. Therefore, the Agency is requiring at a minimum the use of coveralls and chemical resistant gloves by workers. To further reduce worker risks as much as practical towards negligible levels, the Agency is requiring mixers and loaders to wear coveralls over long pants and long-sleeved shirts (double layer protection), chemical resistant gloves and a chemical resistant apron to protect against spills or splashing. Double layer protection should not result in heat stress to workers during mixing and loading operations as may be the case during applications which require longer periods of time to complete. Additionally, double layer protection is not warranted for applicators of ethalfluralin because the Agency estimates these workers' upper bound carcinogenic risk estimates are already negligible (10^{-6} or less) with single layer protection. Additional exposure reduction measures, such as employing closed mixing/loading systems or enclosed cabs would not be cost effective and are not being required. These requirements and other worker protective measures, including reentry into treated areas are discussed below and in Section V.

Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/Applicators)

For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be established based on the acute toxicity of the end-use product. For occupational-use products, PPE will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects:

• In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.

• These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

• The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

There are special toxicological concerns (i.e., classification of ethalfluralin as a Group C carcinogen) about ethalfluralin that warrant the establishment of active-ingredient-based PPE requirements, as discussed above.

Handler PPE for Occupational-Use Products

WPS Uses: At this time all of the registered uses of ethalfluralin appear to be within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The minimum (baseline) PPE for all end-use products containing ethalfluralin is coveralls and chemical-resistant gloves for all handlers. The PPE required for mixers and loaders is coveralls over long pants, and long sleeved shirt, chemical resistant-gloves and chemical-resistant apron. Use of this PPE will reduce potential dermal exposure and risks of carcinogenicity as discussed above in the risk assessment, Section III.

NonWPS Occupational Uses: At this time all of the registered uses of ethalfluralin appear to be within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

Handler PPE for Home-Use Products

At this time there appear to be no products containing ethalfluralin that are intended primarily for home use.

Entry Restrictions

Entry Restrictions for Occupational-Use Products

Restricted Entry Interval: Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: product-specific REI's established on the basis of adequate data and interim REI's that are longer than those that would be established under the WPS.

For occupational end-use products containing ethalfluralin as an active ingredient, the Agency is establishing a 24-hour restricted-entry interval pertaining to each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). This recommendation is based on ethalfluralin being categorized as toxicity category II (moderate) for skin irritation potential and classified as a Group C carcinogen. The Agency has found no extenuating circumstance for retaining the 12-hour interim restricted-entry interval placed on ethalfluralin products by PR Notice 93-7. It is noted that the 12-hour interim WPS restricted-entry interval was established because early data indicated that ethalfluralin was in toxicity category III for skin irritation potential.

The Agency notes that the WPS established very specific restrictions on entry during restricted-entry intervals that involves contact with treated surfaces and believes that these existing WPS protections are sufficient to mitigate post-application exposures of workers who contact ethalfluralin-treated soil. The

Agency also notes that if ethalfluralin has been correctly incorporated, workers may enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction if they are performing tasks that do not involve contact with the soil subsurface.

Early Entry PPE -- Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If EPA has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient.

2. If EPA has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Since ethalfluralin is classified as toxicity category II for skin irritation potential and eye irritation potential and is categorized as a Group C carcinogen, the PPE required for early entry is coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks and protective eyewear.

Non-target Aquatic Organisms and Plants

The Agency concludes that certain uses of ethalfluralin at the maximum application rate (1.7 lbs. a.i./A) may result in risk of acute toxicity to freshwater fish and invertebrates, non-target plants, and marine/estuarine invertebrates based on the risk assessment described above in Section C.2(b). This assessment suggests unincorporated spray applications to cucurbit and alfalfa fields may result in aquatic residue levels that equal or slightly exceed the Agency's Restricted Use Level of Concern (LOC) for freshwater fish and invertebrates. Also, unincorporated applications of ethalfluralin to cucurbit fields may result in some risks to semi-aquatic non-target plants inhabiting wet areas in the vicinity of these fields.

This assessment also suggests that incorporated granular and spray applications to dry bean and sunflower fields may result in aquatic residues that slightly exceed the Agency's LOC for endangered freshwater fish species. Also

unincorporated spray applications may exceed this LOC for endangered species of freshwater fish and invertebrates and marine/estuarine invertebrates.

The following mitigation measures would likely reduce risks to nonendangered and endangered aquatic animal and plant species.

Alfalfa: Ethalfluralin's use on alfalfa is currently limited under Special Local Needs (FIFRA, Section 24(c)) registrations for the states of Oregon and Washington. Alfalfa grown in these states is irrigated by flood or furrow irrigation practices due to low rainfall. To reduce contamination of aquatic areas with ethalfluralin residues from treated alfalfa fields and therefore to reduce risks to aquatic organisms, the following risk reduction measure is required. Ethalfluralin products labeled for use on alfalfa must include the following statement:

"For flood or furrow irrigation, do not allow the tail waters from the first irrigation after application to enter aquatic habitats."

Dry Beans and Sunflowers: Risks of concern from ethalfluralin use on dry beans and sunflowers are limited to endangered freshwater fish species. Risk mitigation measures for these uses will be effected under the Agency's Endangered Species Program discussed below.

Cucurbits: Based on the potential risks as described above from the use of ethalfluralin on cucurbit fields all ethalfluralin products labeled for use on cucurbits must include the following statement:

"Due to risk to plants and animals in aquatic habitats that receive run-off containing this product, use of controls such as a vegetative buffer strip to filter such water flow from recently treated fields is recommended."

For cucurbits, employment of a vegetative filter strip may reduce the risk to aquatic fish, invertebrates, and plant species. However, at this time the Agency is not imposing specific risk mitigation requirements. Instead, the Agency is requiring that the above statement be placed on the product labeling that alerts users to the risks and recommends controls on runoff into aquatic habitats such as vegetative strips. In addition, the Agency is working with the Natural Resources Conservation Service to develop detailed guidance on vegetative filters, such as the design and construction of different kinds of vegetative filters and an education program for registrants and farmers. This guidance may be available in 1995. More specific requirements for the use of a vegetative filter strip may be imposed in the future.

3. Endangered Species Protection

The Agency has concerns about the exposure of threatened and endangered plant and animal species to ethalfluralin as discussed above in the science assessment chapter.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in the near future and have enforceable county-specific bulletins available. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

Limitations in the use of ethalfluralin will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

4. Labeling Rationale

In order to remain in compliance with FIFRA, it is the Agency's position that the labeling of all registered pesticide products containing ethalfluralin must comply with the Agency's current pesticide labeling requirements.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of ethalfluralin for the above eligible uses has been reviewed and determined to be substantially complete, except for residue chemistry data to support cucurbits. Additional data are needed to fulfill requirements for the studies listed below.

Additional confirmatory data are required to upgrade the following product chemistry guidelines: 61-1; 62-1; 62-2; and 62-3;

Additional residue data for cucurbits are required to upgrade the following residue chemistry guidelines: 171-4(a); 171-4(k). Confirmatory field trial data are required for cucurbits (postplant-preemergence), and a third metabolism study is required (cucurbits). These residue data are outstanding as well as new data to support the postemergence and posttransplant applications on cucurbits. This residue data is currently being reviewed by the Agency. The Agency anticipates reviewing these data in time to allow reregistration of all end-use products labeled for use on cucurbits.

Field trial data are required for residues of ethalfluralin in/on alfalfa hay and forage, pea and bean hay and forage, soybean hay and forage, and peanut hay. These data are considered confirmatory;

The Agency has concluded that residues of ethalfluralin from up to 10x dietary burden in food-producing animals would not be quantifiable (< 0.05 ppm). This is considered a Category 3 use (40 CFR §180.6), which states that it is not possible to establish with certainity whether finite residues will be incurred, but there is no reasonable expectation of finite residues. Therefore, the existing tolerances (expressed in terms of ethalfluralin *per se*) for eggs, milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep should be revoked.

Data pertaining to the nitrosamine content are outstanding; nitrosamine analysis is required since ethalfluralin contains a tertiary alkylamine

2. Labeling Requirements for Manufacturing-Use Products

The following label statement is required on all manufacturing-use products:

Effluent Discharge Labeling Statements

All manufacturing-use or end-use products that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the following revised effluent discharge labeling statement.

"This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All affected products distributed or sold by registrants and distributors (supplemental registrants) must bear the above labeling by October 1, 1995. All products distributed or sold by persons other than registrants or supplemental registrants after October 1, 1997 must bear the correct labeling. Refer to PR Notice 93-10 or 40 CFR 152.46(a)(1) for additional information.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Worker Protection Standard

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

Other Labeling Requirements

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

The Agency is requiring the following labeling statements to be located on all end-use products containing ethalfluralin that are intended primarily for occupational use:

Application Restrictions:

> "Do not apply this product in a way that will contact workers or other persons, either directly or through spray drift. Only protected handlers may be in the area during application"

Engineering Controls:

> "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides, 40 CFR 170.240 (d) (4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:

> "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

> "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

> "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

> "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

In addition, because ethalfluralin is classified as a skin sensitizer, the Agency requires that the following statement appear on all ethalfluralin labels in the "Hazards to Humans (and Domestic Animals) section of the Precautionary Statements:

> "This product may cause skin sensitization reactions in certain individuals."

The minimum (baseline) PPE for all end-use products containing ethalfluralin is: coveralls and chemical-resistant gloves for all handlers.

The PPE required for mixers and loaders is coveralls over long pants, and long-sleeved shirt, chemical-resistant gloves, and chemical-resistant apron.

The PPE required for early entry is coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks and protective eyewear.

For occupational end-use products containing ethalfluralin as an active ingredient, the Agency is establishing a 24-hour restricted-entry interval pertaining

to each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS).

Registrants may add the following statement to their labeling in the Agricultural Use Requirements box immediately following the restricted entry interval:

> "Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

Grazing, foraging, and haying restrictions must be removed from the labels, except sunflower forage.

Environmental hazard requires the following labeling statement:

> "This product is toxic to fish and aquatic invertebrates. Do not apply directly to any body of water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate."

For application to alfalfa the following statement is required:

> "For flood or furrow irrigation, do not allow the tail waters from the first irrigation after application to enter aquatic habitats."

For application to cucurbit fields the following statement is required:

> "Due to risk to plants and animals in aquatic habitats that receive run-off containing this product, use of controls such as a vegetative buffer strip to filter such water flow from recently treated fields is recommended."

Effluent Discharge Labeling Statements

Refer to subsection A. above for labeling requirements for effluent discharge.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for

50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell ethalfluralin products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to your products.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES													
ALFALFA				Use Group: TERRESTRIAL FEED CROP									
Soil incorporated treatment., Postemergence., Low pressure ground sprayer.	EC	NA	1.688 lb A	*	NS	NS	NS	NS	NS	NS	OR		C14, GF9
	EC	NA	1.688 lb A	*	NS	NS	NS	NS	NS	NS	WA		C14, GM2, GO1
	EC	NA	1.5 lb A	*	NS	NS	NS	NS	NS	NS	WY		C14, GF9
BEANS, DRIED-TYPE				Use Group: TERRESTRIAL FOOD+FEED CROP									
Soil incorporated treatment., Fall., Spreader.	G	NA	1.7 lb A 1.5 lb A 1.3 lb A	F M C	NS	NS	NS	NS	NS	NS	ND		C94, CAD, GC9
Soil incorporated treatment., Preplant., Low pressure ground sprayer.	DF	NA	1.65 lb A 1.5 lb A 1.3 lb A	F M C	NS	NS	NS	NS	NS	NS		MT	C46, C94, CAD, GC9
	EC	NA	1.688 lb A 1.5 lb A 1.313 lb A	F M C	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9
Soil incorporated treatment., Preplant., Spreader.	EC	NA	1.688 lb A 1.5 lb A 1.313 lb A	F M C	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9
	G	NA	1.7 lb A 1.5 lb A 1.3 lb A	F M C	NS	NS	NS	NS	NS	NS			C94, CAD, GC9
	G	NA	1.7 lb A 1.5 lb A 1.3 lb A	F M C	NS	NS	NS	NS	NS	NS	ND		C94, CAD, GC9
CUCUMBER				Use Group: TERRESTRIAL FOOD CROP									
Soil broadcast treatment., Postplant., Low pressure ground sprayer.	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS		NJ	C46, C94, CAD, GC9
MELONS				Use Group: TERRESTRIAL FOOD CROP									
Soil broadcast treatment., Postplant., Low pressure ground sprayer.	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS		NJ	C46, C94, CAD, GC9

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
MELONS, WATER			Use Group: TERRESTRIAL FOOD CROP										
Soil broadcast treatment., Postplant., Low pressure ground sprayer.	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	NJ		C46, C94, CAD, GC9
PEANUTS			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil incorporated treatment., Preplant., Low pressure ground sprayer.	DF	NA	1.1 lb A .95 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS	MT		C46, C94, CAD, GC9
	EC	NA	1.125 lb A .938 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9
Soil incorporated treatment., Preplant., Spreader.	EC	NA	1.125 lb A .938 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9
PEANUTS (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil incorporated treatment., Preplant., Low pressure ground sprayer.	EC	NA	1.125 lb A .938 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9
Soil incorporated treatment., Preplant., Spreader.	EC	NA	1.125 lb A .938 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9
	G	NA	1.15 lb A .95 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS			C94, CAD, GC9
PEAS, DRIED-TYPE			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil incorporated treatment., Preplant., Low pressure ground sprayer.	DF	NA	.75 lb A .75 lb A	M C	NS	NS	NS	NS	NS	NS	MT, CA		C46, C94, CAD, GC9
	EC	NA	.75 lb A .75 lb A	M C	NS	NS	NS	NS	NS	NS	CA		C46, C92, C94, GC9
Soil incorporated treatment., Preplant., Spreader.	EC	NA	.75 lb A .75 lb A	M C	NS	NS	NS	NS	NS	NS	CA		C46, C92, C94, GC9
	G	NA	.75 lb A .75 lb A	M C	NS	NS	NS	NS	NS	NS	CA		C94, CAD, GC9

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
PUMPKIN			Use Group: TERRESTRIAL FOOD CROP										
Soil broadcast treatment., Postplant., Ground.	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	IL		C46
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	KY		C46
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	OH		C46
SOYBEANS (UNSPECIFIED)			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil incorporated treatment., Preplant., Low pressure ground sprayer.	DF	NA	1.3 lb A 1.1 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS	MT		C46, C94, CAD, GC9
	EC	NA	1.313 lb A 1.125 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9
Soil incorporated treatment., Preplant., Spreader.	EC	NA	1.313 lb A 1.125 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9
	G	NA	1.3 lb A 1.15 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS			C94, CAD, GC9
SQUASH (SUMMER)			Use Group: TERRESTRIAL FOOD CROP										
Soil broadcast treatment., Postplant., Ground.	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	IL		C46
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	KY		C46
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	OH		C46

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SQUASH (SUMMER) (con't)			Use Group: TERRESTRIAL FOOD CROP (con't)										
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	OR		C46
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	WA		C46
SQUASH (WINTER)			Use Group: TERRESTRIAL FOOD CROP										
Soil broadcast treatment., Postplant., Ground.	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	IL		C46
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	KY		C46
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	OH		C46
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	OR		C46
	EC	NA	1.688 lb A 1.5 lb A 1.125 lb A	F M C	NS	NS	NS	NS	NS	NS	WA		C46
SUNFLOWER			Use Group: TERRESTRIAL FOOD+FEED CROP										
Soil incorporated treatment., Fall., Spreader.	G	NA	1.7 lb A 1.5 lb A 1.3 lb A	F M C	NS	NS	NS	NS	NS	NS	ND		C94, CAD, GC9
Soil incorporated treatment., Preplant., Low pressure ground sprayer.	DF	NA	1.1 lb A .95 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS		MT	C46, C94, CAD, GC9
	EC	NA	1.125 lb A .938 lb A .75 lb A	F M C	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SUNFLOWER (con't)			Use Group: TERRESTRIAL FOOD+FEED CROP (con't)										
Soil incorporated treatment., Preplant., Spreader.	EC	NA	1.125 lb A	F	NS	NS	NS	NS	NS	NS			C46, C92, C94, GC9
			.938 lb A	M									
			.75 lb A	C									
	G	NA	1.15 lb A	F	NS	NS	NS	NS	NS	NS			C94, CAD, GC9
			.95 lb A	M									
			.75 lb A	C									
	G	NA	1.7 lb A	F	NS	NS	NS	NS	NS	NS	ND		C94, CAD, GC9
			1.5 lb A	M									
			1.3 lb A	C									
End of USES ELIGIBLE FOR REREGISTRATION													

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES INELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
CUCUMBER	Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION												
Band treatment., Postemergence., Low pressure ground sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS		NJ	C46, C94, CAD, GC9
Band treatment., Posttransplant., Low pressure ground sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS		NJ	C46, C94, CAD, GC9
MELONS	Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION												
Band treatment., Postemergence., Low pressure ground sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS		NJ	C46, C94, CAD, GC9
Band treatment., Posttransplant., Low pressure ground sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS		NJ	C46, C94, CAD, GC9
MELONS, WATER	Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION												
Band treatment., Postemergence., Low pressure ground sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS		NJ	C46, C94, CAD, GC9
Band treatment., Posttransplant., Low pressure ground sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS		NJ	C46, C94, CAD, GC9
PUMPKIN	Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION												
Band treatment., Postemergence., Ground.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	IL		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	KY		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OH		C46
Band treatment., Posttransplant., Ground.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	IL		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	KY		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OH		C46
SQUASH (SUMMER)	Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION												
Band treatment., Postemergence., Ground.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	IL		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	KY		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OH		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OR		C46

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES INELIGIBLE FOR REREGISTRATION													
FOOD/FEED USES (con't)													
SQUASH (SUMMER) (con't)				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION (con't)									
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	WA		C46
Band treatment., Posttransplant., Ground.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	IL		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	KY		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OH		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OR		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	WA		C46
SQUASH (WINTER)				Use Group: TERRESTRIAL FOOD CROP USES INELIGIBLE FOR REREGISTRATION									
Band treatment., Postemergence., Ground.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	IL		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	KY		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OH		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OR		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	WA		C46
Band treatment., Posttransplant., Ground.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	IL		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	KY		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OH		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	OR		C46
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	WA		C46

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	Minimum Interval between Applications (days)
Restr. Entry Interv (days)	Restricted Entry Interval (days)
PRD Report Date	LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	Non-specific
C	Coarse
M	Medium
F	Fine
O	Others

FORMULATION CODES

DF	WATER DISPERSIBLE GRANULES (DRY FLOWABLE)
EC	EMULSIFIABLE CONCENTRATE
G	GRANULAR

ABBREVIATIONS

AN	As Needed
NA	Not Applicable
NS	Not Specified (on label)
UC	Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	Dosage Can Not be Calculated
No Calc	No Calculation can be made
W	PPM calculated by weight
V	PPM Calculated by volume
U	Unknown whether PPM is given by weight or by volume
cwt	Hundred Weight
nnE-xx	nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C14 : Grown for seed only.
C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
C94 : Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas.
CAD : Do not apply directly to water or wetlands.
GC9 : Do not graze or forage crop grown in treated soil or cut for hay or silage.

USE LIMITATIONS CODES (Cont.)
GF9 : Do not graze treated crop or allow hay, seeds or seed screenings from treated crop to be used for food or feed.
GM2 : Do not harvest forage or hay from treated areas.
GO1 : Do not graze or cut green forage or hay for livestock feed.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
CA : California
IL : Illinois
KY : Kentucky
MT : Montana
ND : North Dakota
NJ : New Jersey
OH : Ohio
OR : Oregon
WA : Washington
WY : Wyoming

APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case ethalfluralin covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to ethalfluralin in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Ethalfluralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	all	Upgradable, (42042501, 42370201)
61-2A	**Starting Materials & Mnfg. Process**	all	42042501, 42779201
61-2B	**Formation of Impurities**	all	42042501
62-1	**Preliminary Analysis**	all	Upgradable, (42370201)
62-2	**Certification of limits**	all	Upgradable, (42370201)
62-3	**Analytical Method**	all	Upgradable, (42370201)
63-2	**Color**	all	00135194
63-3	**Physical State**	all	00135194
63-4	**Odor**	all	00135194
63-5	**Melting Point**	all	00135194
63-6	**Boiling Point**	--	Not Applicable
63-7	**Density**	all	42308801
63-8	**Solubility**	all	00135194
63-9	**Vapor Pressure**	all	42437201
63-10	**Dissociation Constant**	--	Not applicable
63-11	**Octanol/Water Partition**	all	41890101
63-12	**pH**	--	Not applicable
63-13	**Stability**	all	41613901, 41086401, 42929601

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail**	A,B	00094760
71-2A	**Avian Dietary - Quail**	A,B	00094761
71-2B	**Avian Dietary - Duck**	A,B	00094762
71-4A	**Avian Reproduction - Quail**	A,B	00094764
71-4B	**Avian Reproduction - Duck**	A,B	00094763
72-1A	**Fish Toxicity Bluegill**	A,B	00135183, 41613902
72-1B	**Fish Toxicity Bluegill - TEP**	A,B	42176401
72-1C	**Fish Toxicity Rainbow Trout**	A,B	00135183, 41613903
72-2A	**Invertebrate Toxicity**	A,B	00094770
72-2B	**Invertebrate Toxicity - TEP**	A,B	42176402
72-3A	**Estuarine/Marine Toxicity - Fish**	A,B	41613904
72-3B	**Estuarine/Marine Tox - Mollusk**	A,B	41613905, 42889801
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A,B	41613906
72-4A	**Early Life Stage Fish**	A,B	41994901
72-4B	**Life Cycle Invertebrate**	A,B	41613907, 42930101
122-1A	**Seed Germination/Seedling Emergence**	A,B	41613911, 41613913
122-1B	**Vegetative Vigor**	A,B	42904201
122-2	**Aquatic Plant Growth**	A,B	41613912
123-1A	**Seed Germination/Seedling Emergence**	A,B	41613911, 41613913
123-1B	**Vegetative Vigor**	A,B	42904201

Data Supporting Guideline Requirements for the Reregistration of Ethalfluralin

REQUIREMENT		USE PATTERN	CITATION(S)
141-1	**Honey Bee Acute Contact**	A,B	41613914
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B	41613908
81-2	**Acute Dermal Toxicity - Rabbit**	A,B	41613909
81-3	**Acute Inhalation Toxicity - Rat**	A,B	41977601
81-4	**Primary Eye Irritation - Rabbit**	--	41613910
81-5	**Primary Dermal Irritation - Rabbit**	--	41613909
81-6	**Dermal Sensitization - Guinea Pig**	--	00070683
82-1A	**90-Day Feeding - Rodent**	A,B	00094774, 00094775, 00094777
82-1B	**90-Day Feeding - Dog**	A,B	00135193
82-2	**21-Day Dermal - Rabbit**	A,B	00145767
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B	00094776, 00094778
83-1B	**Chronic Feeding Toxicity - Dog**	A,B	00153371
83-2A	**Oncogenicity - Rat**	A,B	00094776
83-2B	**Oncogenicity - Mouse**	A,B	00094778
83-3A	**Developmental Toxicity - Rat**	A,B	00153370
83-3B	**Developmental Toxicity - Rabbit**	A,B	00129057
83-4	**2-Generation Reproduction - Rat**	A,B	00094784, 00070682, 42300301
84-2A	**Gene Mutation (Ames Test)**	A,B	00128693, 00128694, 00128695
84-2B	**Structural Chromosomal Aberration**	A,B	00152219, 00128696
84-4	**Other Genotoxic Effects**	A,B	00094786

Data Supporting Guideline Requirements for the Reregistration of Ethalfluralin

REQUIREMENT		USE PATTERN	CITATION(S)
85-1	**General Metabolism**	A,B	00094789, 00132820, 42822901
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A,B	00094805
161-2	**Photodegradation - Water**	A,B	41613916
161-3	**Photodegradation - Soil**	A,B	41613917
162-1	**Aerobic Soil Metabolism**	A,B	41613918
162-2	**Anaerobic Soil Metabolism**	A,B	41613919
162-3	**Anaerobic Aquatic Metabolism**	A,B	42930102
163-1	**Leaching/Adsorption/Desorption**	A,B	41890102, 42496601
163-2	**Volatility - Lab**	A,B	42496601
164-1	**Terrestrial Field Dissipation**	A,B	41613920, 41978101
165-4	**Bioaccumulation in Fish**	A,B	41994902
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	A,B	00145955, 43394001 data gap for cucurbits
171-4B	**Nature of Residue - Livestock**	A,B	42487801, 42487802, 42902201, 42929001
171-4C	**Residue Analytical Method - Plants**	A,B	PAM Vols. I and II
171-4D	**Residue Analytical Method - Animal**	A,B	PAM Vols. I and II
171-4E	**Storage Stability**	A,B	42456401, 42456402, 42456403, 42456404, 42456405, 42487801, 42487802, 42511101, 42511102, 42511103, 42511104, 42542602, 42626001

Data Supporting Guideline Requirements for the Reregistration of Ethalfluralin

REQUIREMENT		USE PATTERN	CITATION(S)
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	--	Waived
171-4K	**Crop Field Trials**	A,B	
	Beans, dry		41613923
	Peas, dry		42542602
	Soybean		42542603
	Beans, vines and hay		Data gap
	Peas, vines and hay		Data gap
	Soybean, forage and hay		Data gap
	Alfalfa, forage and hay		Data gap
	Cucumbers		Data gap
	Squash		Data gap
	Melons		Data Gap
	Peanuts		42542601
	Sunflower, seed		41613921, 41613922
171-4L	**Processed Food -**	A,B	
	Peanuts		42456405
	Soybean		42456404
	Sunflower, seed		41613922
165-1	**Rotational Crops (Confined)**	A,B	42930103

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Ethalfluralin

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBLIOGRAPHY

MRID	CITATION
--------	DowElanco. 1991. Worker Mixer, Loader, Applicator Exposure to Ethalfluralin. DowElanco Study No. AAC 9054.
--------	Ethalfluralin labels (062719-00184, 062719-00120, 062719-00188).
--------	Fisher, B. and Pettigrew, H., 1994. Memorandum dated 8/3/94 to R. Landolt/TB II Subject: Ethalfluralin, Quantitative Risk Assessment, Comparison of 2 Q_1^*'s (old,1981 vs new,1994), from Combined Data from Two Chronic/Oncogenicity Studies in Fischer 344 Rats, 1981.
--------	Hoerger, F.D. and E.E. Kenaga. 1972. Pesticide residues on plants correlation of representative data as a basis for estimation of their magnitude in the environment. Environmental Quality, Academic Press, New York, I:9-28.
--------	Ioannov M. and van Gemert, M., 1994. Toxicology Endpoint Selection Document for Ethalfluralin dated May 19, 1994; Memo to James Kariya, Larry Dorsey, Esther Saito, Debra Edwards, Edward Sager, William Burnam, George Ghali, and Caswell File.
--------	McLaughlin, P. 1994. (Draft) Toxicology Review for Reregistration Eligibility Document on Ethalfluralin. Memorandum revised date 7/6/94 from McLaughlin (HED) to Chow (HED).
--------	Telephone conversation between Tim Leighton (Versar 703-750-3000) and Ed Day (DowElanco 317-337-3667) on 7/28/94.
--------	U.S. EPA, 1990. Ethalfluralin OREB Phase 4 Review dated 10/26/90 reviewed by L. Morris, A. Nielsen and C. Trichilo.
--------	U.S. EPA. 1992. Comparative Analysis of Acute Avian Risk from Granular Pesticides. OPP Avian Granular Project Team, USEPA, Washington, D.C. 71 pp.
--------	U.S. EPA, 1994. Label Use Information System Report for Ethalfluralin Dated 5/26/94; (Cover Memo May 31, 1994).
--------	Urban, D.J. and N. J. Cook. 1986. Hazard Evaluation Division Standard Evaluation Procedure: Ecological Risk Assessment. USEPA/OPP, EPA-540/9-85-001. 96 pp.

BIBLIOGRAPHY

MRID	CITATION
00094774	Adams, E.R.; Gossett, F.O.; Hoffman, D.G.; Owen, N.V.; Emmerson, J.L.; Morton, D.M. 1978. Three Month Oral Toxicity Study of Ethalfluralin (94961; EL-161) in Mice. Study No. M-9286. Unpublished study conducted by Lilly. (also 070678-E)
00094775	Adams, E.R.; Owen, N.V.; Hoffman, D.G. 1979. A One-Year Dietary Toxicity Study with Ethalfluralin (Compound 94961) in the Fisher 344 Rat. Study No. R-257. Unpublished study conducted by Lilly. (also 070678-F)
00094776	Adams, E.R.; Owen, N.V.; Emmerson, J.L. 1981. Two-Year Dietary Evaluation of Ethalfluralin in the Fisher 344 Rat. Study Nos. R-267, R-277. Unpublished study conducted by Lilly. (also 070678-G, 92062013)
00094777	Adams, E.R.; Owen, N.V.; Emmerson, J.L. 1981. A One-Year Dietary Toxicity Study with Ethalfluralin (Compound 94961) in the B6C3F1 Mouse. Study No. M-9157. Unpublished study conducted by Lilly. (also 070679-A)
00094778	Adams, E.R. 1981. A Two-Year Dietary Evaluation of Ethalfluralin (Compound 94961) in the B6C3F1 Mouse. Study Nos. M-9167, M-9177. Unpublished study conducted by Lilly. (also 070680-A)
00094784	Adams, E.R.; Owen, N.V.; Emmerson, J.L. 1981. A Multi-Generation Reproduction Study with Ethalfluralin (Compound 94961) in the Fischer 344 Rat. Study Nos R-68, R-738, R-1248. Unpublished study conducted by Lilly. (also 070682-F)
00094786	Probst, G.S.; Neal, S.B.; Adams, E.R. 1980. The Effect of Ethalfluralin (Lilly Compound 94961) on the Induction of DNA Repair Synthesis in Primary Cultures of Adult Rat Hepatocytes. Study No. 791120-263. Unpublished study conducted by Lilly. (also 0070682, 250475-C, 00128695)
00094788	Adams, E.R.; Pierson, C.L.; Arthur, B.H. 1981. Guinea Pig Sensitization Studies of Ethalfluralin. Study Nos. G-9530, G-00379. Unpublished studies conducted by Lilly. (also 070683-A)
00094789	Adams, E.R.; Hanasono, G.K.; Hoffman, D. 1981. Metabolism and Disposition of Ethalfluralin in Male Wistar Rats. No study number. Unpublished study conducted by Lilly. (also 070683-B)

BIBLIOGRAPHY

MRID	CITATION
00094805	Mosier, J.W.; Sullivan, W.L.; Saunders, D.G. (1976) A Hydrolysis Study on the Herbicide Ethalfluralin. (Unpublished study re-ceived Feb 4, 1982 under 1471-122; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:070676-D)
00128693	Thompson, C.; Adams, E.; Probst, G. 1983. The Effect of Ethalfluralin on the Induction of Bacterial Mutation Using a Modification of the Ames Test. Study No. 830404GPA1169. Unpublished study submitted by Lilly. (also 250475-A)
00128694	Rexroat, M.; Adams, E.; Probst, G.; et al. (1983) The Effect of Ethalfluralin (Compound 94961) on the Induction of Reverse Mutations in Salmonella typhimurium Using the Ames Test: Studies 830307AMS1169, 830404AMS1169 and 830425AMS1169. (Unpublished study received Jun 9, 1983 under 1471-122; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:250475-B)
00128695	Rexroat, M.; Adams, E.; Probst, G. 1983. The Effect of Ethalfluralin (Compound 94961) on the Induction of Reverse Mutations in Salmonella typhimurium Using the Ames Test. Studies 830307-, 830404-, 830425-AMS1169. Unpublished studies submitted by Lilly. (also 250475b)
00128696	Oberly, T.; Bewsey, B.; Adams, E. 1983. The Effect of Ethalfluralin (Compound 94961) on the Induction of Forward Mutation at the Thymidine Kinase Locus of L5178Y Mouse Lymphoma Cells. Study 830208MLA1169. Unpublished study submitted by Lilly. (also 250475-D)
00129057	Byrd, R.; Adams, E.R.; Fisher, L.F.; et al. 1983. A Teratology Study of Ethalfluralin Administered Orally to Butch Belted Rabbits. Study No. B01383. Unpublished study conducted by Lilly. (also 250596-A)
00132820	Adams, E.R.; Bridge, T.L.; Van Lier, R.B.L. 1982. Percutaneous Absorption of 14C-Ethalfluralin in Monkeys. Study Nos. M-6162, PO-3282. Unpublished study conducted by Lilly. (also 072180-B)
00135191	Adams, E.; Gossett, F.; Hoffman, D; et al. 1978. Three- Month Oral Toxicity Study of Ethalfluralin (94961, EL-161) in Rats. Study No. R936. Unpublished study submitted by Lilly. (also 097326-E)

BIBLIOGRAPHY

MRID **CITATION**

00135193 Gossett, F.; Koenig, G.; Harris, P. 1974. Subacute Toxicity of EL-161 Technical Grade in Dogs. Study No. D3733. Unpublished study submitted by Lilly. (also 097326-G)

00135194 Elanco Products Co. (1975) The Name, Chemical Identity and Composition of the Pesticide Chemical: [Ethalfluralin]. (Compilation; unpublished study received Aug 24, 1978 under 1471-EX-63; CDL:073327-A)

00145767 Brown, G. 1985. Subchronic (21-day) Dermal Toxicity Study in New Zealand White Rabbits with Technical Ethalfluralin. Study No. B01384. Unpublished study conducted by Lilly. (also 00257855)

00145955 Berard, D.F. (1984) Characterization of Radioactive Residues in Peanut Nutmeats and Hulls from Plants Grown in Soil Treated with ^{14}C Ethalfluralin. Report No. ABC -0223. Also Radioactive residues in Bean Seeds, Pods, and Stems from Plants Grown in Soil Treated with ^{14}C Ethalfluralin. Report No. ABC-0212. Unpublished study conducted and submitted by Eli Lilly and Company, Greenfield, IN, 199 p.

00152219 Mosesso, P.; Dean, B.; Forster, R. 1985. Test Substance: Ethalfluralin. Chromosome Aberrations in Chinese Hamster Ovary Cells (CHO) In Vitro. Study No. 095003M02385. Unpublished study prepared by Life Science Research Roma. (also 259342)

00153370 Robinson, K. it al. 1985. A Teratology Study of Orally Administered Ethalfluralin (EL-161) in the Rat. Study No. 82182. Unpublished study conducted by Bioresearch Labs. (also 260434-B, 92062017)

00153371 Adams, E.; Bernhard, N. 1985. The Toxicity of Ethalfluralin Administered Orally to Beagle Dogs for One Year. Study No. DO 1684. Unpublished study conducted by Lilly. (also 00262711, 260434-A, 92062014)

41086401 Carpenter, M.; Fennessey, M. (1988) Determination of the Photolysis of [Carbon 14]-Ethalfluralin in Aqueous Solution: ABC Second Amended Final Report #36868. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 76 p.

BIBLIOGRAPHY

MRID	CITATION
41613901	Hudson, J.; Smith, C. (1990) Ethalfluralin Technical: Chemical Stability: Lab Project Number: TIL909004. Unpublished study prepared by DowElanco. 6 p.
41613908	Adams, E.R.; Gardner, J.B.; Sites, D.L. 1990. The Acute Toxicity of Ethalfluralin (EL-161, Compound 094961) Administered Orally to the Fischer 344 Rat. Study No. B09490. Unpublished study conducted by Lilly.
41613909	Adams, E.R.; Rock, G.L.; St. Clair, R.L. 1990. The Acute Dermal Toxicity and Primary Dermal Irritation of Ethalfluralin (EL-161, Compound 094961) in the New Zealand White Rabbit. Study No. B01390. Unpublished study conducted by Lilly.
41613910	Adams, E.R.; Rock, G.L.; St. Clair, R.L. 1990. The Acute Ocular Irritation of Ethalfluralin (EL-161, Compound 094961) in the New Zealand White Rabbit. Study No. B01490. Unpublished study conducted by Lilly.
41613916	Carpenter, Mark and Melinda Fennessey. 1988. Determination of the Photolysis Rate of ^{14}C-Ethalfluralin in Aqueous Solution. Submitted by Eli Lilley and Company, Greenfield, Indiana. Performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri.
41613917	Dykes, John. 1990. Determination of the Photolysis Rate of ^{14}C-Ethalfluralin on the Surface of Soil. Submitted by Elli Lilly and Company, Greenfield, Indiana. Performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri.
41613918	Graper, L.K. 1990. Aerobic Soil Metabolism of ^{14}C-Ethalfluralin in Sandy Loam Soil. Submitted and performed by Dow Elanco, Plant Science Chemical Development, Greenfield, IN.
41613919	Graper, L.K. 1990. Anaerobic metabolism of ^{14}C-Ethalfluralin in Sandy Loam Soil. Submitted and performed by Dow Elanco, Plant Science Chemical Development, Greenfield, IN.
41613921	Conn, R. (1990) Magnitude of the Residue of Ethalfluralin in or on Sunflower: Lab Project Number: MKL-003-89-12: Rpt. No. AAC-9017. Unpublished study prepared by McKenzie Labs, Inc. 132 p.

BIBLIOGRAPHY

MRID	CITATION
41613922	Conn, R. (1990) Magnitude of the Residue of Ethalfluralin in the Processed Fractions of Sunflower: Lab Project Number: MKL-003-89-12: E8909: E8910: Rpt. No. AAC-9044. Unpublished study prepared by McKenzie Labs, Inc. 146 p.
41613923	Conn, R. (1990) Magnitude of the Residue of Ethalfluralin in or on Dry Beans: Lab Project Number: MKL-003-89-12: RPT. NO. AAC-9016. Unpublished study prepared by McKenzie Labs, Inc. 201 p.
41890101	Day, E. (1991) Octanol/Water Partition Coefficient of Ethalfluralin: Lab Project Number: EWD9104. Unpublished study prepared by Lilly Analytical Chemistry Dept. 9 p.
41890102	Sanders, Donald G. and Fred L. Powers. 1991. Ethalfluralin Aged Soil Leaching Study. Submitted and performed by Dow Elanco, Plant Science Chemical Development, Greenfield, IN.
41977601	Wolff, R.; Allen, D.; Williams, er al. 1991. The Acute The Acute Inhalation Toxicity in the Fischer 344 Rat of Technical Ethalfluralin. Lab Project Number: R17191. Unpublished study conducted by Lilly.
41978101	Decker, O.D. 1991. Ethalfluralin dissipation study. Laboratory ID No. AAC8712. Unpublished study performed and submitted by DowElanco, Indianapolis, IN.
41994902	Woodburn, K.B., S.C. Hansen, T. Ball and P.C. Wilga. 1991. Ethalfluralin: Bioconcentration in rainbow trout, *Oncorhynchus mykiss*. Laboratory ID No. ES-DR-0233-3655-1. Unpublished study performed by The Environmental Toxicology and Chemistry Research Laboratory, Dow Chemical, Midland, MI and submitted by DowElanco, Indianapolis, IN.
42042501	Handy, P.; Reinhart, R. (1991) Product Composition of Technical Ethalfluralin: Lab Project Number: PRH9104. Unpublished study prepared by DowElanco, Formulation & Environ. Chem. Lab. 7 p.
42300301	Hoyt, J.A.; Owen, N.V.; Adams, E.R. 1992. A 7-Month Multigeneration Bridging Study of Ethalfluralin (EL-161, Compound 094061) Administered in

BIBLIOGRAPHY

MRID	CITATION

the Diet to Fischer 344 Rats. Study Nos. R16890, R16990. Unpublished study conducted by Lilly.

42308801 Stolz, W. (1992) Density of Sonalan Technical: A Summary: Lab Project Number: FOR92006. Unpublished study prepared by DowElanco. 10 p.

42370201 Handy, P. (1992) Series 62: Analysis and Certification of Ethalfluralin, Technical Grade Active Ingredient: Lab Project Number: GH-C 2757. Unpublished study prepared by DowElanco. 53 p.

42437201 Decker, O. (1987) Vapor Pressure of Ethalfluralin: Lab Project Number: ODD8721. Unpublished study prepared by Lilly Research Laboratories. 11 p.

42437202 Saunders, D. G. and F. L. Powers. 1987. Adsorption and Desorption of Ethalfluralin in Soil. Submitted and performed by DowElanco, Greenfield, Indiana.

42456401 Conn, R. (1992) Magnitude of Residue of Ethalfluralin in or on Dry Beans: Lab Project Number: E8908: MKL-003-89-12. Unpublished study prepared by Stewart Agricultural Research Services, Inc. in cooperation with McKenzie Laboratories, Inc. 363 p.

42456402 Conn, R. (1992) Magnitude of Residue of Ethalfluralin in or on Sunflower: Lab Project Number: E8909: MKL-003-89-12. Unpublished study prepared by Stewart Agricultural Research Services, Inc. in cooperation with McKenzie Laboratories, Inc. 295 p.

42456403 Conn, R. (1992) Magnitude of Residue of Ethalfluralin in the Processed Fractions of Sunflowers: Lab Project Number: E8909: E8910: MKL-003-89-12. Unpublished study prepared by Stewart Agricultural Research Services, Inc. in cooperation with The Texas A & M University System and McKenzie Laboratories, Inc. 161 p.

42456404 Conn, R. (1992) Magnitude of Residue of Ethalfluralin in the Processed Fractions of Soybeans: Lab Project Number: AAC9001: MKL-006-90-12. Unpublished study prepared by Stewart Agricultural Research Services, Inc. in cooperation with The Texas A & M University System and McKenzie Laboratories, Inc. 188 p.

BIBLIOGRAPHY

MRID	CITATION
42456405	Conn, R. (1992) Magnitude of Residue of Ethalfluralin in the Processed Fractions of Peanuts: Lab Project Number: AAC9002: MKL-006-90-12. Unpublished study prepared by Stewart Agricultural Research Services, Inc. in cooperation with The Texas A & M University System and McKenzie Laboratories, Inc. 186 p.
42487801	Magnussen, J. (1992) Nature of [carbon 14] Ethalfluralin Residues in Ruminants: Lab Project Number: PLN 91003. Unpublished study prepared by DowElanco. 60 p.
42487802	Graper, L. (1992) Nature of [Carbon 14] Ethalfluralin Residues in Chickens: Lab Project Number: MET91089. Unpublished study prepared by DowElanco. 90 p.
42496601	Kesterson, Abbe. 1992. Laboratory volatility of [14C]-ethalfluralin. Performed by PTRL East, Inc. Submitted by DowElanco, Greenfield, Indiana.
42511101	Conn, R.; Rogers, J. (1992) Storage Stability of Ethalfluralin: Residues in Cucumber: Lab Project Number: MKL-004-90-12. Unpublished study prepared by McKenzie Labs, Inc. 218 p.
42511102	Conn, R.; Rogers, J. (1992) Storage Stability of Ethalfluralin: Residues in Peanut Nutmeat: Lab Project Number: MKL-004-90-12. Unpublished study prepared by McKenzie Labs, Inc. 218 p.
42511103	Conn, R.; Rogers, J. (1992) Storage Stability of Ethalfluralin: Residues in Soybean Seed: Lab Project Number: MKL-004-90-12. Unpublished study prepared by McKenzie Labs, Inc. 218 p.
42511104	Conn, R.; Rogers, J. (1992) Storage Stability of Ethalfluralin: Residues in Soybean Processed Fractions: Lab Project Number: MKL-005-90-12. Unpublished study prepared by McKenzie Labs, Inc. and Texas A & M University. 124 p.
42542601	Shackelford, D.; Decker, O.; Ervick, D. (1992) Magnitude of Residue Study of Ethalfluralin in Peanuts: Lab Project Number: RES91048. Unpublished study prepared by DowElanco. 105 p.

BIBLIOGRAPHY

MRID	CITATION
42542602	Shackelford, D.; Decker, O.; Ervick, D. (1992) Magnitude of Residue Study of Ethalfluralin in Dry Peas: Lab Project Number: RES91050. Unpublished study prepared by DowElanco. 84 p.
42542603	Shackelford, D.; Decker, O.; Ervick, D. (1992) Magnitude of Residue Study of Ethalfluralin in Soybean: Lab Project Number: RES91049. Unpublished study prepared by DowElanco. 142 p.
42626001	Rutherford, B.; Griggs, R. (1993) Storage Stability of Ethalfluralin in Sunflower Seed: Lab Project Number: RES91106. Unpublished study prepared by DowElanco. 30 p.
42779201	Stolz, W. (1993) Technical Ethalfluralin - Beginning Materials Specification Sheets: Lab Project Number: WS021193. Unpublished study prepared by DowElanco. 32 p.
42822901	Eschbach, J.C.; Hackett, D. 1993. Absorption, Distribution, and Elimination of 14C-Ethalfluralin in Rats. Study No. DR-0233-3655-001. Unpublished study conducted by Bio/dynamics.
42902201	Magnussen, J. (1992) Supplemental Data to: (Carbon 14) Ethalfluralin Ruminant Nature of Residue Study: Lab Project Number: PLN91003: PLN91003.01. Unpublished study prepared by DowElanco, North American Environ. Chemi. Lab. 28 p.
42929001	Graper, L. (1992) Supplemental Data to: Nature of (Carbon 14) Ethalfluralin Residues in Chickens: (MRID No. 42487802): Lab Project Number: MET91089: MET91089.01. Unpublished study prepared by North American Environmental Chemistry Lab. 39 p.
42929601	Stolz, W. (1993) Determination of the Stability of Ethalfluralin Technical to Selected Metals and Metal Ions at Elevated Temperatures: Lab Project Number: FOR93036. Unpublished study prepared by DowElanco. 10 p.
42930102	Lawrence, B, S.G. Mobley, and A. Kesterson. 1993. Anaerobic aquatic metabolism of [^{14}C]ethalfluralin. PTRL Project ID: 650. Unpublished study performed by PTRL East, Richmond, KY and submitted by DowElanco, Indianapolis, IN.

42930103 O'Neal, S.; Johnson, T. (1993) A Confined Rotational Crop Study with (Carbon 14)-Ethalfluralin: Lab Project Number: 576: 1509. Unpublished study by PTRL East, Inc. 312 p.

43394001 Berard, D. (1994) Supplemental Data for (carbon 14) Ethalfluralin Nature of Residue Studies in Peanuts and Beans: Lab Project Number: ABC-0212.01: ABC-0223.01: 0212.01/ABC-0223.01. Unpublished study prepared by DowElanco North American Environ. Chemistry Lab. 49 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to ethalfluralin. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for ethalfluralin and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Ethalfluralin RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,…. of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the com-plete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, …250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in mul-tiple volumes is permissible so long as the entire study is pag-inated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10,

151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with pet-itions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d) (1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for

microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous corres-pondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a tran-smittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____
Signature Name

Company Name _____

Company Contact: _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

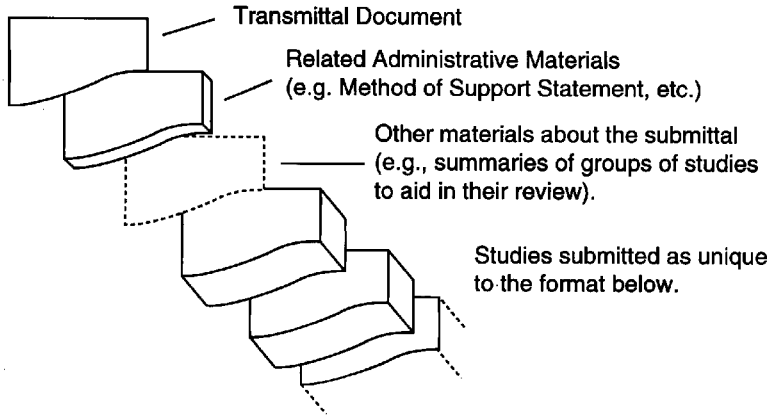
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

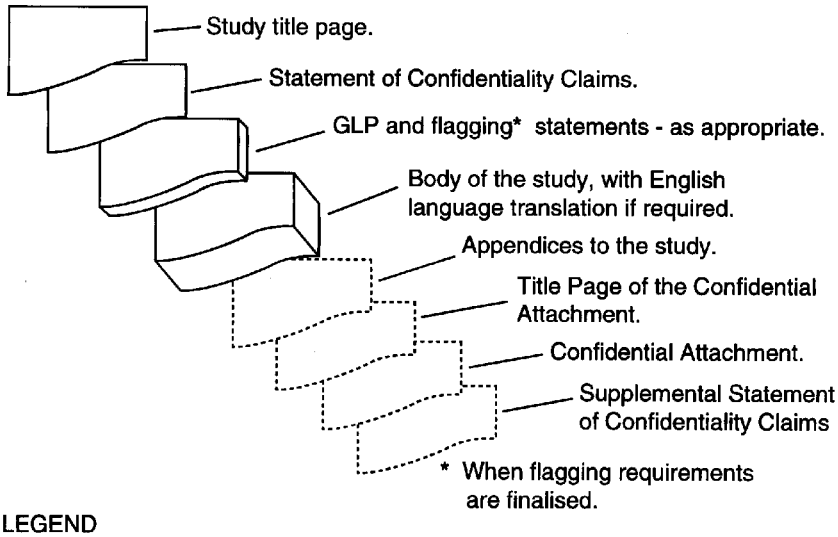
Submitter_____

ATTACHMENT 7.

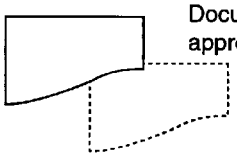
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



PR Notice 91-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients
Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the

certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,**" all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Generic Data Call-In

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or,

3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

The Attachments to this Notice are:

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally,

the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Attachment 2) and the Requirements Status and Registrant's Response Form (Attachment 3). The Data Call-In Response Form must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5

on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,

b. every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this

Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and option 6b and 7 on the Data Call-In Response Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data --

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the

Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data --

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide

EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development --

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study --

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the

protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies --

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a

particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form; or,

b. fulfill the commitment to develop and submit the data as required by this Notice; or,

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

C. EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Federal Insecticide, Fungicide, and Rodenticide Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice

should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Attachment 2) and a completed Requirements Status and Registrant's Response Form (Attachment 3) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Peter Caulkins, Acting Director
Special Review
and Reregistration Division

Attachment 1. Chemical Status Sheet

ETHALFLURALIN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing ethalfluralin.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of ethalfluralin. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this ethalfluralin Generic Data CallIn (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for ethalfluralin are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on ethalfluralin are needed. These data are needed to fully complete the reregistration of all eligible ethalfluralin products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Tom Myers at (703) 308-8074.

All responses to this Notice for the generic data requirements should be submitted to:

Tom Myers, Chemical Review Manager
Accelerated Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Ethalfluralin

Attachment 2. Generic DCI Response Forms Inserts (Form A) plus Instructions

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form Items 5 through 7 must be completed by the registrant as appropriate Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily cancelled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and

incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

Attachment 3. Requirements Status and Registrants' Response Forms Inserts (Form B) plus Instructions

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

A. Terrestrial food
B. Terrestrial feed
C. Terrestrial non-food

D.	Aquatic food
E.	Aquatic non-food outdoor
F.	Aquatic non-food industrial
G.	Aquatic non-food residential
H.	Greenhouse food
I.	Greenhouse non-food crop
J.	Forestry
K.	Residential
L.	Indoor food
M.	Indoor non-food
N.	Indoor medical
O.	Indoor residential

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP _ *	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

*See: guideline comment

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to

the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-ln Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless

modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

Attachment 4. List of Registrant(s) sent this DCI (Insert)

APPENDIX G. Product Specific Data Call-In

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments A through G; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified

in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-

In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not

submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the

study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted
without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of

the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Peter Caulkins, Acting Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

Attachment 1. Chemical Status Sheet

ETHALFLURALIN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing ethalfluralin.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of ethalfluralin. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this ethalfluralin Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for ethalfluralin are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on ethalfluralin are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible ethalfluralin products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of ethalfluralin, please contact Tom Myers at (703) 308-8074.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Bruce Kapner, (703) 308-8013
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Ethalfluralin

Attachment 2. Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed

"**Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data

requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" **form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 3. Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-3. Completed by EPA. Note the unique identifier number assigned by EPA in item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guidelines reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use patters (s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/ or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. lt is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.

Item 9. Enter Only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product my be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed " Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the require data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be require to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

NOTE:You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF PRODUCTS CONTAINING ETHALFLURALIN AS THE ACTIVE INGREDIENT FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient ethalfluralin (Benzenamine, N-ethyl-N-[2-methyl-2-propenyl]-2,6-dinitro-4-[trifluoromethyl]-[9CI]) the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table 1 displays the batches for the active ingredient Ethalfluralin.
Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	62719-184	ethalfluralin … 10.00%	granular
	ND90000200	ethalfluralin … 10.00%	granular
	ND91000200	ethalfluralin … 10.00%	granular
2	34704-610	ethalfluralin … 36.1%	liquid
	62719-120	ethalfluralin … 36.1%	liquid
	IL91000300	ethalfluralin … 36.1%	liquid
	KY93000100	ethalfluralin … 36.1%	liquid
	OH91000400	ethalfluralin … 36.1%	liquid
	OR91000400	ethalfluralin … 36.1%	liquid
	OR91000800	ethalfluralin … 36.1%	liquid
	WA91000500	ethalfluralin … 36.1%	liquid
	WA92000900	ethalfluralin … 36.1%	liquid
	WY92000400	ethalfluralin … 36.1%	liquid

Table 2 lists the products the Agency was unable to batch. These products were considered not to be similar to other products in terms of acute toxicity. The registrant of these products is responsible for meeting the acute toxicity data requirements for these products.

Table 2.

Registration Number	Percent Active Ingredient	Form
62719-132	ethalfluralin … 95%	powder
62719-139	ethalfluralin … 50%	powder
62719-188	ethalfluralin … 31.5%	liquid

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at $<$ 0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 0.1%.
2.____ Degree of accountability or closure > ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at > 0.1% and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*_____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*_____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C (+2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of < 2 or > 11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share Data Compensation Forms, Confidential Statement of Formula Form and Instructions

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved

OMB No. 2070-0106
2070-0057

Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-96)

APPENDIX H. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-002 January 1995

R.E.D. FACTS

Ethalfluralin

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2260, ethalfluralin.

Use Profile

Ethalfluralin is a selective herbicide used for the preemergence control of annual grasses and broadleaf weeds in certain food and feed crops. Marketed under the trade name Sonalan, ethalfluralin may be used in growing a variety of grain, seed, and cucurbit crops. The greatest amounts of ethalfluralin are used in growing soybeans, dry beans, and sunflower seeds. Granular, dry flowable, and emulsifiable concentrate formulations are registered. Products may be applied preplant, postplant prior to emergence, postemergence, or post-transplant as a soil incorporated, band, or broadcast application using ground equipment.

Ethalfluralin is used only outdoors, in agriculture--no residential uses are registered. Use practice limitations prohibit applying ethalfluralin to any body of water or wetland.

Regulatory History

Ethalfluralin was conditionally registered as a herbicide for use on dry peas, dry beans, soybeans, and cucurbits, from November 1983 until December 1, 1985. EPA determined that ethalfluralin's benefits outweighed its cancer risks during that time period. Tolerances, or maximum residue limits in food and feed commodities, were established. Later, data were

submitted that allowed full registration of ethalfluralin, and several new uses were added.

In December 1990, EPA issued a data call-in notice under phase IV of the accelerated reregistration program. At present, six products are registered containing the active ingredient ethalfluralin including one technical (manufacturing use) product and five end-use products.

Human Health Assessment

Toxicity

Ethalfluralin causes moderate eye irritation and moderate to severe skin irritation, and has been placed in Toxicity Category II (the second-highest of four acute toxicity categories) for these effects. It also is a skin sensitizer. Ethalfluralin otherwise is of relatively low acute toxicity. It has been placed in Toxicity Category III for inhalation effects, and Toxicity Category IV for oral and dermal effects.

Subchronic toxicity studies using mice and rats resulted in changes in liver and kidney weights, decreased weight gain, and changes in blood and enzyme activity. A study using beagle dogs resulted in changes in the liver, blood and cholesterol. A study using rabbits resulted in severe skin irritation.

A chronic toxicity and carcinogenicity study using rats resulted in mammary gland tumors in female rats at mid and high doses. EPA concluded on June 8, 1994, that ethalfluralin should be classified as a Group C, possible human carcinogen, based on the results of that study. A second study in mice caused liver cell, blood and enzyme changes, as well as increased liver, kidney and heart weights in females, and decreased body weight gain. A study using beagle dogs resulted in changes in the blood, bone marrow, enzymes and liver.

Although a developmental toxicity study in rats did not show effects, a study using rabbits resulted in maternal effects (abortions and decreased food consumption), and developmental toxicity effects including increased resorptions, abnormal skull development, and variations in the sturnum.

No treatment-related effects were noted on reproduction parameters in two reproductive toxicity studies using rats. Ethalfluralin was weakly mutagenic in two types of mutagenicity studies but negative for mutagenicity in two other studies.

Dietary Exposure

People may be exposed to residues of ethalfluralin through the diet. Tolerances or maximum residue limits have been established for ethalfluralin residues in/on plants (dry beans, cucurbit vegetables, peanuts, peanut hulls, dry peas, soybeans, and sunflower seeds) and in animal commodities (eggs, milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep). (Please see 40 CFR 180.416.) All of these tolerances are established at 0.05 parts per million (ppm). Ethalfluralin residues are not likely to concentrate in processed food, so no

food or feed additive tolerances are established or required. Residues were not found in rotational crops so relevant tolerances need not be established.

EPA has assessed most existing ethalfluralin tolerances. Additional confirmatory data are required for the postplant-preemergence application use of ethalfluralin on cucurbits (cucumbers, melons, and squash) to reassess the adequacy of the tolerances established. New data also are required for the postemergence and posttransplant applications to cucurbits. These data are **not** considered confirmatory, however, since EPA lacks data which would allow an interim assessment of the residues. Thus, at this time, the postemergence and posttransplant uses of ethalfluralin on cucurbits **are not eligible** for reregistration. If data from cucurbit studies currently underway are not adequate, these uses will have to be removed from ethalfluralin product labels.

In addition, ethalfluralin tolerances for animal commodities must be revoked. Ethalfluralin residues in animals at up to ten times the usual dietary burden are not quantifiable. If it is not possible to determine finite residues with certainty, and if it is unlikely that there are any residues, the Agency's policy is not to establish tolerances, or to revoke existing ones.

Finally, since label restrictions on grazing, haying, and foraging generally are no longer permitted, such restrictions for beans, peas, soybeans, peanuts and alfalfa must be removed from all ethalfluralin labels.

EPA has assessed the dietary risk posed by ethalfluralin. In its analysis, the Agency included the existing tolerances for cucurbits (though adequate data are not available for reregistration) and animal commodities (though these tolerances must be revoked), to reflect a worst case scenario.

The upper bound dietary risk estimate for the U.S. population is 6.2×10^{-5} based on all the published tolerances for ethalfluralin. However, EPA is revoking the tolerances for meat, milk, poultry, and eggs, based on the presumption that there are undetectable, finite residues in these food items. When cancer risk is calculated without these tolerances, the upper bound dietary risk is 5.7×10^{-7}, a negligible risk.

For the overall U.S. population, chronic exposure from all existing ethalfluralin tolerances represents 2% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The Anticipated Residue Contribution (ARC), a more accurate estimate of dietary exposure which takes into account percent of crop treated and other chemical- and use-specific information, still represents only 2% of the RfD for the overall population. For the most highly exposed subgroup, non-nursing infants, chronic exposure from all existing tolerances represents 9% of the RfD, while the ARC is only 4% of the RfD. Therefore, chronic dietary risk appears to be minimal.

Acute exposure to the subgroup of greatest concern, females age 13 and older (women of childbearing age), results in a Margin of Exposure (MOE) of 25,000 for developmental toxicity. EPA believes MOEs of 100

or greater represent a negligible risk for that toxicological endpoint. Therefore, acute dietary risk to ethalfluralin is not of concern.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders and applicators) may be exposed to ethalfluralin during applications to agricultural crops. Because ethalfluralin is a possible human carcinogen, EPA assessed exposure and risk to workers in four major exposure scenarios. While workers in three of the scenarios have risks that are considered negligible, commercial mixers/loaders using the liquid/dry flowable formulation with ground application equipment are estimated to have an extra cancer risk of 1×10^{-5}.

To mitigate this worker risk, EPA is requiring use of minimum, baseline personal protective equipment (PPE), including coveralls and chemical resistant gloves, by all ethalfluralin handlers. To further reduce their risks, mixers and loaders must wear coveralls over long pants and long-sleeved shirts--a double layer of protection--as well as chemical resistant gloves and a chemical-resistant apron to protect against spills or splashing.

Post-application exposure to ethalfluralin should be minimal, as long as the pesticide is applied and incorporated into soil correctly, or unless the task involves contact with the soil subsurface. EPA is requiring a 24-hour restricted entry interval (REI), strengthening the interim 12-hour REI established by the Worker Protection Standard (WPS). However, if ethalfluralin has been incorporated correctly, workers may enter the treated area during the REI without PPE, if they are performing tasks that do not involve contact with the soil surface. When contact with the soil surface is necessary, early entry workers must wear appropriate PPE including coveralls over a short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks, and protective eyewear.

Human Risk Assessment

Ethalfluralin causes moderate eye and skin irritation but otherwise is of relatively low acute toxicity. However, it causes mammary gland tumors and is classified as a quantifiable Group C, possible human carcinogen. Ethalfluralin also is a developmental toxicant.

Although people may be exposed to residues of ethalfluralin through the diet, both acute and chronic dietary risks appear to be minimal. Risks to handlers (mixers/loaders/applicators) are of concern, but are being reduced by requiring minimum, baseline PPE for all handlers plus additional PPE for mixers and loaders. A more stringent, 24-hour REI is being imposed, as is early entry PPE.

Environmental

Environmental Fate

Assessment

Although the data submitted for reregistration are not complete, EPA has sufficient information at this time to provide an overall qualitative assessment for ethalfluralin.

Ethalfluralin is expected to dissipate by binding to soil particles and then degrading both aerobically and anaerobically. In the field, ethalfluralin did not leach, and it is not expected to contaminate ground water. Because ethalfluralin is structurally similar to trifluralin, which has been detected in ground water in 10 of 21 states, EPA cannot make a complete assessment of ethalfluralin until its assessment of trifluralin is finished.

There is some potential for ethalfluralin to reach surface waters on eroded soil particles. In surface waters, it is expected to photodegrade and to degrade rapidly in anaerobic sediments by electrochemical reactions. Ethalfluralin was not volatile in the laboratory; however, no assessment of its spray drift potential is possible from the submitted data.

Ecological Effects

Technical ethalfluralin is practically nontoxic to bobwhite quail on an acute oral basis, and to bobwhite quail and mallard ducks on a subacute dietary basis. It does not appear to cause reproductive effects in birds.

Ethalfluralin end-use products are practically nontoxic to slightly toxic to small mammals on an acute oral and dermal basis. Technical ethalfluralin also is practically nontoxic to honey bees.

Technical ethalfluralin is highly to very highly toxic to rainbow trout and bluegill sunfish. The formulated product also is highly toxic to bluegill sunfish. Since ethalfluralin persists in soils and is very highly toxic to fish, an acute toxicity sediment study was submitted. This study shows that ethalfluralin released from soil sediments can be lethal to sunfish when concentrations in water reach 17 to 58 parts per billion (ppb). In an early life stage toxicity test with freshwater fish, ethalfluralin affected larval length and weight in trout.

In invertebrate toxicity studies, technical ethalfluralin is very highly toxic and the formulated product is slightly toxic to *Daphnia magna* on an acute basis. In a life cycle study using daphnids, reproduction was the most sensitive parameter affected. Ethalfluralin is highly toxic to marine/estuarine fish, mollusks, and shrimp on an acute basis.

In terrestrial plant studies, ethalfluralin affected parameters including radicle length, plant height and weight, and shoot dry weight (in cotton).

Ecological Effects Risk Assessment

Wildlife may be exposed to ethalfluralin either by consuming contaminated food items (such as seeds, fruit, or insects), or by ingesting granules. Birds, for example, may ingest granules as a source of grit. However, no acute or chronic risks to endangered or nonendangered birds are expected to occur from eating food items, and no undue risk is expected from granular applications. Minimal risk to mammals is anticipated from the present ethalfluralin uses.

Ground applications of ethalfluralin could result in potential risks to aquatic organisms from runoff and drift. Although neither high acute risk nor chronic risk to aquatic organisms is anticipated, the restricted use trigger has been exceeded for freshwater organisms, and endangered species triggers are exceeded for freshwater organisms and estuarine/marine invertebrates.

For unincorporated applications, some risk is posed to nontarget semi-aquatic plants in the vicinity of treated fields. However, no risk to plants is posed from soil-incorporated applications. High risk to nontarget aquatic plants is not expected.

Endangered species levels of concern are exceeded for freshwater organisms and estuarine/marine invertebrates from unincorporated applications; for freshwater fish from incorporated applications; and for plants growing in wet areas receiving channelized runoff from treated sites (from unincorporated applications). Limitations may be imposed on the use of ethalfluralin to protect threatened and endangered species when EPA implements the Endangered Species Protection Program, later in 1995.

Risk Mitigation

Since ethalfluralin is considered a possible human carcinogen and a developmental toxicant, EPA is requiring the following risk mitigation measures, as discussed earlier:

- To reduce risks to workers, require all handlers to use minimum, baseline PPE, and require mixers and loaders to use additional PPE, as specified in the RED. Extend the REI from 12 to 24 hours and require early entry PPE, as detailed in the RED document.
- To reduce risks to freshwater fish, invertebrates, and certain nontarget plants from unincorporated granular and spray applications:
  - Prohibit alfalfa irrigation tail waters from entering aquatic habitats.
  - Recommend use of runoff controls such as vegetative buffer strips to filter water flow from recently treated cucurbit fields before it reaches aquatic habitats. EPA and the Natural Resources Conservation Service are developing guidance on such vegetative filters, and the Agency may require their use in the future.
  - Require compliance with the Endangered Species Protection Program, when it goes into effect.

Additional Data Required

EPA is requiring the following generic studies for ethalfluralin to confirm its regulatory assessments and conclusions:

Additional generic product chemistry studies;

Additional residue chemistry studies, confirmatory and new field trial data, and a third metabolism study for cucurbits (due by May 31, 1995);

Field trial data for alfalfa hay and forage, pea and bean hay and forage, soybean hay and forage, and peanut hay;

Nitrosamine content and analysis studies.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All ethalfluralin end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Worker Protection Standard

Personal Protective Equipment (PPE) Requirements

Products containing ethalfluralin may contain more stringent PPE, but in no case may require less stringent PPE than the following requirements. Producers must compare the PPE requirements in this section with those on current labeling and retain the more protective.

Handler PPE for Occupational Use Products - For all uses of ethalfluralin, which are within the scope of the WPS, the minimum or baseline PPE required for pesticide handlers (mixers, loaders, and applicators) is:

- coveralls, and
- chemical-resistant gloves.

The PPE required for mixers and loaders is:

- coveralls over long pants and long-sleeved shirt;
- chemical-resistant gloves; and
- chemical-resistant apron.

Early Entry PPE - The PPE required for early entry is:

- coveralls over short-sleeved shirt and short pants;
- chemical-resistant gloves;
- chemical-resistant footwear plus socks; and
- protective eyewear.

Entry Restrictions

WPS Uses - A 24-hour restricted entry interval (REI) is required for all currently registered ethalfluralin uses, all of which are within the scope of the Worker Protection Standard (WPS).

Registrants may add the following statement to their labeling in the Agricultural Use Requirements box immediately following the restricted entry interval:

"Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

Other Labeling Requirements

Grazing, foraging and haying restrictions must be removed from ethalfluralin labels, except sunflower forage.

Directions for Use - The labels of all ethalfluralin end-use products must be revised to bear the following statements under this section:

Application Restrictions:

"Do not apply this product in a way that will contact workers or other persons, either directly or through spray drift. Only protected handlers may be in the area during application."

Engineering Controls:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for Agricultural Pesticides, 40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Precautionary Statements - Because ethalfluralin is classified as a skin sensitizer, the Agency requires that the following statement appear on all labels in the Hazards to Humans and Domestic Animals section of these statements:

"This product may cause skin sensitization reactions in certain individuals."

Environmental Hazard - The labels of all ethalfluralin end-use products must bear the following statement under this section:

"This product is toxic to fish and aquatic invertebrates. Do not apply directly to any body of water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do

not contaminate water when disposing of equipment washwaters or rinsate."

For application to alfalfa, the following statement is required:

"For flood or furrow irrigation, do not allow the tail waters from the first irrigation after application to enter aquatic habitats."

For applications to cucurbit fields, the following statement is required:

"Due to risk to plants and animals in aquatic habitats that receive run-off containing this product, use of controls such as a vegetative buffer strip to filter such water flow from recently treated fields is recommended."

Effluent Discharge Statements - All end-use and manufacturing-use products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the following labeling statement:

"This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Regulatory Conclusion

The use of currently registered products containing ethalfluralin, in accordance with labeling amended to reflect the risk mitigation measures imposed by this RED, generally will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products, except postemergence and posttransplant applications to cucurbits, are eligible for reregistration.

EPA is unable to make a reregistration eligibility decision regarding the postemergence and posttransplant uses of ethalfluralin on cucurbits because the Agency does not yet have the residue chemistry data required to support these uses. A registrant is conducting the required studies, which are due to the Agency by May 31, 1995. Once EPA reviews and accepts the studies, these cucurbit uses also will be considered eligible for reregistration.

Ethalfluralin products will be reregistered once the required product specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for ethalfluralin during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To

obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV.*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the ethalfluralin RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the ethalfluralin RED, or reregistration of individual products containing ethalfluralin, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.